ISSN 2515-8260 Volume 10, Issue 01, 2023

Original Research

Evaluation of rationality of drug promotional literature using WHO guidelines in a tertiary care hospital in North Karnataka

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Abstract

Introduction: Drug promotional literatures are one of the important sources of drug information to the physicians provided by pharmaceutical companies through medical representatives. Information provided in the promotional literature should be factual, evidence based, unambiguous and balanced(benefits and risks)**.**

Objective: To evaluate the rationality of drug promotional literature using World Health Organization(WHO) guidelines.

Material and Methods: This is a Cross-sectional, observational study, conducted at the KBN teaching and general hospital, attached to KBN University-Faculty of Medical Sciences, kalaburagi over a period of 6 months. Drug promotional literature was collected from the out patient departments of KBN teaching and general hospital, kalaburagi. Drug monographs, reminder advertisements, drug lists, ayurvedic medicines, literatures promoting medical devices, equipments or orthopedic prosthesis and literature promoting more than two brands were excluded.

Results

We analysed 190 drug promotional literatures (DPL). Of which majority of DPL were of antimicrobial agents (20.52%). Other included drugs acting on cardiovascular system (17.36%), anti-diabetic drugs (16.31%), Analgesic agents (8.94%), and least being DPL on drugs acting on Gastrointestinal tract (2.10%). On analysis as per WHO criteria, all DPL mentioned brand names and generic names. More than 75% of DPL presented the beneficial points of the drug like pharmacological effect(93.15%), clinical indication(85.78%), dosage form and strength of the drug(84.21%), dosing interval(79.47%) and less than 15% of DPL presented data on drug safety like adverse effects(4.73%), precautions and warning(13.15%), contraindications (6.31%), drug interactions(11.05%), special situations (2.63%) and overdosage(1.05%). 91.57% of the DPL mentioned Name and address of manufacturer and distributor for correspondence. Reference to scientific literature was quoted in < 50% of DPL(49.47%) indicating the lapse in providing evidence based scientific information.

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Conclusion: Most of the drug promotional literatures advertised efficacy of the drug, clinical indications and benefits and omitted the data on drug safety, thus only partially following the WHO criteria for drug promotional literature.

Keywords: Drug promotion, World Health Organization(WHO), anti-microbial agents, antidiabetic drugs, Drug brochure

Introduction

"Drug promotion" refers to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs. Information provided in the promotional literature should be factual, evidence based, unambiguous and balanced(benefits and risks).[1]

Pharmaceutical companies are in the business of developing and selling new drugs. These are accepted in health care system through health care professionals, and its availability is of little value unless the prescriber is aware of its existence and has scientific information to use it effectively.[2] Pharmaceutical promotion is a persuasive communication and the major marketing technique of pharmaceutical companies is “direct to physician marketing.” Physicians are contacted by medical representatives, presented with sample drugs, token gifts, reminder articles and also targeted through sponsored continued medical education, advertisements in the medical journals. [3]

Drug promotional literatures are one of the important sources of drug information to the clinicians provided by pharmaceutical companies through medical representatives. It has advantages and disadvantages and ethical issues. It has important bearing on the rational use of drugs, price control mechanisms, manufacture, availability, and the use of essential medicine and the cost of health care, thus making it a central public health issue.[4]

Other sources of drug promotion and information include advertisements in journals, drug bulletins, drug monographs, reminder advertisements, electronic materials, sponsored continued medical education.[4,5]

Promotional activities by pharmaceutical companies are governed by Organization of Pharmaceutical Producers of India (OPPI), self-regulatory code of pharmaceutical marketing practices, January (2007)and the Drug Controller General of India(DCGI). Adherence to the code of conduct is a condition of membership for manufacturer’s association. [6] However, many studies have illustrated that information disseminated through drug advertisements is inconsistent with the code of ethics.[7]

Rationality of the promotional drug literature can be checked as per “World Health Organization criteria for ethical medicinal drug promotion, 1988” since it is the backbone of self-regulatory code of OPPI and International Federation of Pharmaceutical Manufacturers

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and Associations (IFPMA) which is supposed to regulate the promotional activity of pharmaceutical industries.[1]

These promotional activities have the potential for inappropriate prescribing practices by influencing physician's prescribing behavior without necessarily benefiting the patients but contributes to increased health care costs.[4] hence this study was taken up to evaluate the rationality of DPL as per WHO criteria.

Objectives: To evaluate the rationality of drug promotional literature using WHO guidelines

Material and Methods

This is a Cross-sectional, observational study. Study was conducted at Khaja Banda Nawaz (KBN) teaching and general hospital, a tertiary care teaching hospital attached to KBN University-Faculty of Medical Sciences, Kalaburagi.

Study procedure

The study was conducted after getting approval from the institutional ethics committee.

Drug promotional literature was collected from the out patient departments of KBN teaching and General Hospital, Kalaburagi, over a period of 6 months from March 2022-August 2022.

Inclusion criteria

Drug promotional literature collected from the out patient departments of KBN Teaching and General Hospital, Kalaburagi

Exclusion criteria

Drug monographs, reminder advertisements, drug lists, ayurvedic medicines, literatures promoting medical devices, equipments or orthopedic prosthesis and literature promoting more than two brands were excluded.

All the literatures were evaluated by WHO criteria for the fulfilment of each of the following parameters: [1]

1) International Non-proprietary Name (INN) of each active substance.
2) Brand name
3) Pharmacological data: a brief description of pharmacological effects and mechanism of action.
4) Clinical Information:
    a) Clinical Indications
    b) Dosage regimen and relevant pharmacokinetic data: – average dose and range for adults and children
    – dosing interval
    – average duration of treatment
    – special situations: e.g., renal, hepatic, cardiac, or nutritional insufficiencies that require either increased or reduced dosage c) Contra-indications

d) Precautions and warnings (reference to pregnancy, lactation, etc.)
e) Adverse effects (quantify by category, if possible)
f) Drug interactions (include only if clinically relevant; drugs used for self-medication should be included) g) Overdosage:
– brief clinical description of symptoms
– non-drug treatment and supportive therapy
– specific antidotes

5) Pharmaceutical information:
a) Dosage forms
b) Strength of dosage form
c) Excipients
d) Storage conditions and shelf-life (expiry date)
e) Pack sizes
f) Description of the product and package
g) Legal category (narcotic or other controlled drug, prescription or non-prescription
h) Name and address of manufacturer(s) and importer(s)

6) Reference

Statistical analysis

Analysis was done by using SPSS (Statistical Package for the Social Sciences) software programme, version 25. Variables were summarized and descriptive statistics was used to analyze the data. The data were expressed as percentage.

Results

Antimicrobial agents were the most promoted group (20.52%), and we found only 2.10% of DPL on drugs acting on gastrointestinal tract, and 16.31% of antidiabetic drugs which was disease specific in table 1.

Table 1: Drug promotional literatures according to pharmacological groups

Class of Drugs	Frequency	Percentage
Antimicrobial agents	39	20.52
Drugs acting on cardiovascular system	33	17.36
Anti diabetic drugs	31	16.31
Drugs acting on central nervous system	29	15.26
Drugs acting on respiratory system	21	11.05
Analgesic agents	17	8.94
Haematinics	9	4.73
Drugs acting on blood	7	3.68
Drugs acting on gastrointestinal system	4	2.10
Total	190	100

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Table 2. Analysis of drug promotional Literature (DPL) according to WHO criteria.

WHO Criteria	DPL fulfilling criteria (n)	Percentage (%)
International non-proprietary names	190	100
Brand name	190	100
Pharmacological effects	177	93.15
Clinical indications	163	85.78
Average dose for adults & children	15	7.89
Dosing interval	151	79.47
Adverse effects	09	4.73
Special situations	05	2.63
Contra-indications	12	6.31
Precautions and warnings	25	13.15
Drug interactions	21	11.05
Over dosage	02	1.05
Pharmaceutical information: Dosage form and strength	160	84.21
Name and address of manufacturer or distributor	174	91.57
Reference to scientific literature as appropriate	94	49.47

In Table 2, on analysis of DPL using WHO criteria, all DPL mentioned brand names and generic names. More than 75% of DPL presented the beneficial points of the drug like pharmacological effect(93.15%), clinical indication(85.78%), dosage form and strength of the drug(84.21%), dosing interval(79.47%) and less than 15% of DPL presented data on drug safety like adverse effects(4.73%), precautions and warning (13.15%), contraindications (6.31%), drug interactions(11.05%), special situations(2.63%) and overdosage(1.05%). Name and address of manufacturer and distributor for correspondence was 91.57%. 50% of the DPL did not give any reference to scientific literature.

Classification of reference as per its source:

Of the 190 DPL, 94 DPL quoted references. There were 185 references in these 94 DPL

Table 3. Classification of reference as per its source

Source of references	Number (n)	Percentage(%)
Journals	163	88.10
Website	13	7.02
Textbook	9	4.86
Total number of references cited in 94 DPL	185	100

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Table 4: Reference articles from indexed and non-indexed journals

Journal	Number(n=163)	Percentage(100%)
Indexed Journal	146	89.57
Non-indexed Journal	17	10.42

Of the 185 references quoted, 163 (88.10%) were from journals, 7% from websites and 4.86% textbook reference. Of the 163 journal references 89.57% was indexed and 10.4% non indexed.

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DISCUSSION

Marketing new drugs to physicians is an important strategy adopted by pharmaceutical companies.[7] In Most instances due to busy schedule of a physician/clinician, DPLs becomes the sole source about new drugs/new indications for old drugs. In our study, it was observed that none of the DPLs fulfilled all the criteria laid down by the WHO guidelines. A similar finding was reported in other studies.[7] This suggests that drug promotional companies are more aimed at promoting their product than providing more information to the physicians.[8] In the present study, 20.52% of DPL were of Antimicrobial agents, which indirectly suggest an increased manufacture and promotion of antimicrobials, which can often lead to the misuse or overuse of antimicrobial agents and emergence of resistance. Another important observation was of 16.31% of antidiabetic drug, which also signifies the increased prevalence of diabetes mellitus and subsequent production and marketing of anti diabetic agents. It implies that pharmaceutical companies are targeting diseases which are widely prevalent. This finding was in concordance with a study conducted in Mumbai.[9] Treating physicians should be highly cautious while prescribing the drugs based on information given in DPLs to avoid irrational prescription, prevent drug resistance, adverse effects, and to reduce the cost incurred by patients.[10]

It was observed that all of the DPLs had mentioned brand name, approved generic name, and active ingredient per dosage form, which is similar to a study conducted in Nepal.[11] More than 75% of DPL presented the beneficial points of the drug like pharmacological effect, clinical indication, dosage form, strength of the drug, dosing interval and less than 15% of DPL presented one or two of the risk factors like adverse effects, precautions and warning, contraindications, drug interactions, special situations and overdosage information which is highly unethical. There was no fair balance between benefits and risks(drug safety) and it was comparable to similar studies.[12-15] The information on adverse effects and other relevant risk factors are necessary for the care of the patient and also manage physician time from looking into other source of information, which increases the physician perception towards DPL.[16,17]

Only about 50% of DPL(49.47%) quoted references, which is an essential information for the physicians to practice evidence based medicine. The lack of scientific reference creates doubts on the claims of the drug efficacy by the manufacturer and on the authenticity of information provided.[18,19] physicians must refrain from prescribing such drugs.

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All the brochures were colorful and attractive, but some DPL had irrelevant pictures related to the drugs being promoted with flowery language and unsubstantiated claims regarding efficacy and safety. DPL had used nonspecific representations occupying major area, which could have been utilized appropriately for listing various properties of drugs.[19 - 22]

In view of this study, it is of utmost importance for the treating physician to critically evaluate any source of drug information based on the established guidelines before accepting them as scientific piece of information. Regional Ethics Committee in various metropolitan cities in India receive complaints about unethical drug promotion and report the same to the Drug Controller General of India to take necessary legal steps to regulate pharmaceutical companies to publish DPLs fulfilling the WHO criteria. In many studies on DPL more than 75% of DPL lacked information on drug safety and about 50% satisfied only half of the WHO criteria for rational drug promotion.[21-24] Hence, the treating physicians should be able to critically analyse the drug promotional literature and prescribe only those which are evidence based. This also marks a step towards rational prescription and maintenance of health care system of an individual and thus the health care system of the country.

Conclusion

From the study that has been conducted it can be derived that the pharmaceutical companies are trying to meet the requirements as laid down by the WHO for drug promotional literature but information on drug safety still remains an area of concern. As the DPLs constitute an important source of drug information for the physician, the pharmaceutical companies must follow the criteria laid out by WHO and provide information which is evidence based and must include information on drug safety.

Conflicts of interest: None

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