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RESEARCH ARTICLE

CRITICAL ANALYSIS OF CLAIMS IN DRUG PROMOTIONAL LITERATURE AVAILABLE TO MEDICAL PRACTITIONERS

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Key Messages:-
DPL forms a major marketing technique for pharmaceutical companies for propagating information regarding the brand name, its characteristics, cost, claims, and references cited to support these claims.

Abstract

Context:
Objective: To ascertain whether the pharmaceutical companies are following the World Health Organisation (WHO) criteria for "Ethical Medicinal Drug Promotion 2015" and "Organisation of Pharmaceutical Producers of India (OPPI) Code of Pharmaceutical Marketing Practices, 2019" and to what extent. Also, to evaluate the therapeutic claims made by them in their drug promotional literature (DPL) and to classify them.
Methods: DPL brochures were collected from different pharmaceutical companies from various medical practitioners and assessed for ethical promotion based on guidelines. Therapeutic claims made by them were classified as authentic, exaggerated, controversial, false, misinterpreted, and ambiguous.
Results: A total of 100 DPLs were collected and critically analyzed for authenticity of the content. It was observed that the majority of the DPLs did not comply with the criteria mentioned in the WHO Criteria of Ethical Promotion 2015 and the OPPI Code of Pharmaceutical Practices 2019. International non-proprietary names and the brand name were mentioned by 100% of DPLs. The amount of active ingredients and approved therapeutic indications were mentioned by (99%) and (96%) respectively. The dosage form or regimen was mentioned by 87% of DPLs. Criteria like side effects, precautions/contraindications, and major interactions were mentioned in 28%, 29%, and 14% respectively. Based on the therapeutic claims 23% of the DPLs were found to be authentic and the remaining 77% were extravagant.
Conclusions: This study enabled us to find out to what extent the pharmaceutical industries follow the standard criteria for DPL and evaluate the claims made by them. The majority of the DPLs did not follow ethical guidelines and were inadequate in terms of their adequacy, quality, and reliability.

Introduction:-

There has been a substantial increase in the number of drugs entering the market every day due to advances in medical science. This adds up to the previously existing data. Scientific journals, textbooks, drug compendias, monographs,

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DPLs, drug bulletins, websites, seminars, workshops, conferences, etc are the various sources of drug information.[1] DPL is one of the important methods of providing information about the drug to the physicians.

Pharmaceutical companies discover, develop, manufacture, and market new drugs.[2] They are keen on promoting the sale of new drugs manufactured by them by persuading doctors to recommend their product. Visual aids, flip charts, leave-behinds, advertisements, gifts, and audiovisuals are the diverse modes of promoting drugs.[3] Huge amounts of expenses are spent by pharmaceutical companies every year on sales promotion which includes the cost of sales representatives, medical education programs, commercials, distribution of DPLs, etc.[4] To promote the sale of drugs manufactured by the pharmaceutical companies DPLs form the major marketing techniques which are printed in the form of brochures or pamphlets.[5] Numerous times, it is the main source on which treating physicians rely for refreshing their knowledge about current and novel drugs.[6]

World Health Organization's (WHO) ethical criteria for medicinal drug promotion defines promotion as "all informational and convincing activities by manufacturers and distributors, the result of which is to cause the prescription, supply, purchase, and/or use of the medicinal drug".[7] The "World Health Organization (WHO) Criteria for Ethical Medicinal Drug Promotion 2015" and "The Code of Pharmaceutical Marketing Practices of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) 2012" are two guidelines at the international level.[7,8] "Organisation of Pharmaceutical Producers of India 2019(OPPI)" largely governs the drug promotional activities in India.[9] Adherence to the code of conduct is a condition of membership for the manufacturer's association. However, information disseminated through drug advertisements is inconsistent with the code of ethics.

World Health Organization criteria for "Ethical medicinal drug promotion" is the backbone of the self-regulatory code of OPPI and IFPMA which regulates the promotional activity of pharmaceutical industries.[5] All claims made in the DPL should be reliable, accurate, truthful, informative, balanced, and up-to-date.[7] Therefore, this study was carried out to assess the rationality of claims in the DPLs by critically analyzing the information provided to the medical practitioner to prevent irrational prescribing patterns in medical practice. Promotional literature concentrates more on the commercial aspect rather than the educational aspect. In DPL, reference citations are often given to earn credibility, but it is difficult to trust them because of ambiguous presentation, poor quality, and questionable retrievability. The therapeutically unrelated matter is printed, compromising the space to be given to important pharmacological information.

Due to the busy schedule of medical practitioners and the concise nature of DPL physicians frequently depend on them as primary source of information. If DPLs are critically analyzed and reviewed they can be highly informative where they can provide authentic information but often they are misleading.[5] Extensive marketing influences physicians to the extent that they prescribe new drugs hastily without confirming the rationality of the claims in the DPL which can result in dangerous health-related outcomes e.g. an increase in antibiotic resistance.[10]

Physicians play an important role in analyzing the information provided in a DPL before accepting it as a scientific source of information and complaint about the noncompliant companies to the regulatory authorities.[10] The combined efforts of physicians, pharmaceutical companies, and regulatory bodies are the only way for ethical drug promotion and their rational prescription. This will ensure that information provided in the DPL is up-to-date, accurate, and reliable and not just a marketing strategy.

Aims and Objectives:-

To ascertain whether the pharmaceutical companies are following the "WHO Criteria for Ethical Medicinal Drug Promotion 2015" and "OPPI Code of Pharmaceutical Practices 2019" and to what extent.

To evaluate therapeutic claims made by the pharmaceutical companies in their DPL and other aspects.

Methods:-

1. This is an observational cross-sectional study that was conducted to analyze the authenticity of claims in the drug promotional brochures/pamphlets provided by the pharmaceutical companies to the medical practitioners all over India, carried out after obtaining permission from the Institutional Ethics Committee.

2. Promotional literature in the form of pamphlets or brochures was collected from OPDs, general practitioners, and specialists.
3. Only those promoting allopathic medicine and making at least one therapeutic claim were included in the study.

Exclusion criteria-
DPLs promoting ayurvedic medicines, reminder advertisements, drug monograms, medical devices, and equipment (insulin pump, blood glucometer, etc.,) were excluded.

Criteria for DPL
The brochures were analyzed to study whether they follow the "WHO Criteria for Ethical Medicinal Drug Promotion 2015 "and "OPPI Code of Pharmaceutical Practices 2019"

The following were the WHO criteria to be followed by pharmaceutical industries for the completeness of DPL[7]:
1. The name(s) of the active ingredient(s) using either international nonproprietary names (INN) or the approved generic name of the drug;
2. The brand name;
3. Content of active ingredient(s) per dosage form or regimen;
4. Name of other ingredients known to cause problems;
5. Approved therapeutic uses;
6. Dosage form or regimen;
7. Side-effects and major adverse drug reactions (ADRs);
8. Precautions, contra-indications and warnings;
9. Major interactions;
10. Name and address of manufacturer or distributor;
11. Reference to scientific literature as appropriate.

OPPI Code of Pharmaceutical Practices 2019[9]
All printed promotional materials other than reminder ads have to be legible and include:
1. The name of the product (normally the brand name);
2. The active ingredients, using approved names where they exist;
3. The name and address of the pharmaceutical company or its agent responsible for marketing the product;
4. Date of production of the advertisement;
5. "Abbreviated prescribing information" which should include an approved indication or indications for use with the dosage and method of use, and a statement on contraindications, precautions, and side effects.

The authenticity of therapeutic claims made in promotional literature will be verified by accessing standard literature.

Subsequently, the claims were classified as:
1. Authentic
2. Exaggerated
3. Controversial
4. Misrepresented
5. False
6. Ambiguous

Claims in a DPL[11]

1. Authentic claims:
A claim found to be completely justified according to the reference or evidence quoted in support which is in concordance with the known benefit of drug administration.

2. Extravagant emotional claims:
Claims which were not in concordance with the available scientific data.

Extravagant emotional claims:
Exaggerated:

When a minor advantage of a drug was unnecessarily magnified and the claim extends beyond the actual benefit obtained by the patient. e.g., absence of side effects to amoxicillin.

Controversial:
When the claim was supported by only a few clinical studies in standard literature but contradictory reports were also found questioning the validity of these claim. e.g., no drug interactions with citalopram.

Misrepresented:
When the data from published authentic literature is misrepresented to suit the claims made in the DPL, e.g., lesser excipient-to-drug ratio.

False:
When the claim was totally wrong. When there were no studies to support the use of the drug. e.g., lisinopril is the real ACE inhibitor,ORS promotes concentration and cheer.

Ambiguous:
When a claim was found to be vague in its description. e.g., metoclopramide has a specific behavioral effect on the digestive system.

The statistical analysis for the study was carried out using frequency tables and percentages. Descriptive statistics were used to analyse the data. The data were expressed as percentages.

Pictorial data in the DPLs were analysed to see the following type of picture
- Whether related or unrelated to the drug, treatment or disease
- Presence of bar graphs, line graphs, pie charts, tables

The DPLs were also analysed for additional information such as the cost mentioned and the legibility of the text.

Results:-

In this study, 100 drug DPLs were collected and analysed which revealed 51 were single drug formulations and 49 were fixed-dose combinations. The DPLs were randomly collected from different pharmaceutical companies, both Indian and Multinational companies from different parts of India.

The majority of the DPLs were of drugs in the respiratory system (18%) and endocrine system (18%) thus this being the most promoted pharmacological class of drugs. This was followed by the cardiovascular and renal system (11%), chemotherapy of microbial agents (11%), antihistaminic drugs (9%), vitamins and minerals (7%), anti-inflammatory drugs (4%), gastrointestinal drugs (4%), central nervous system (1%) and others were miscellaneous.

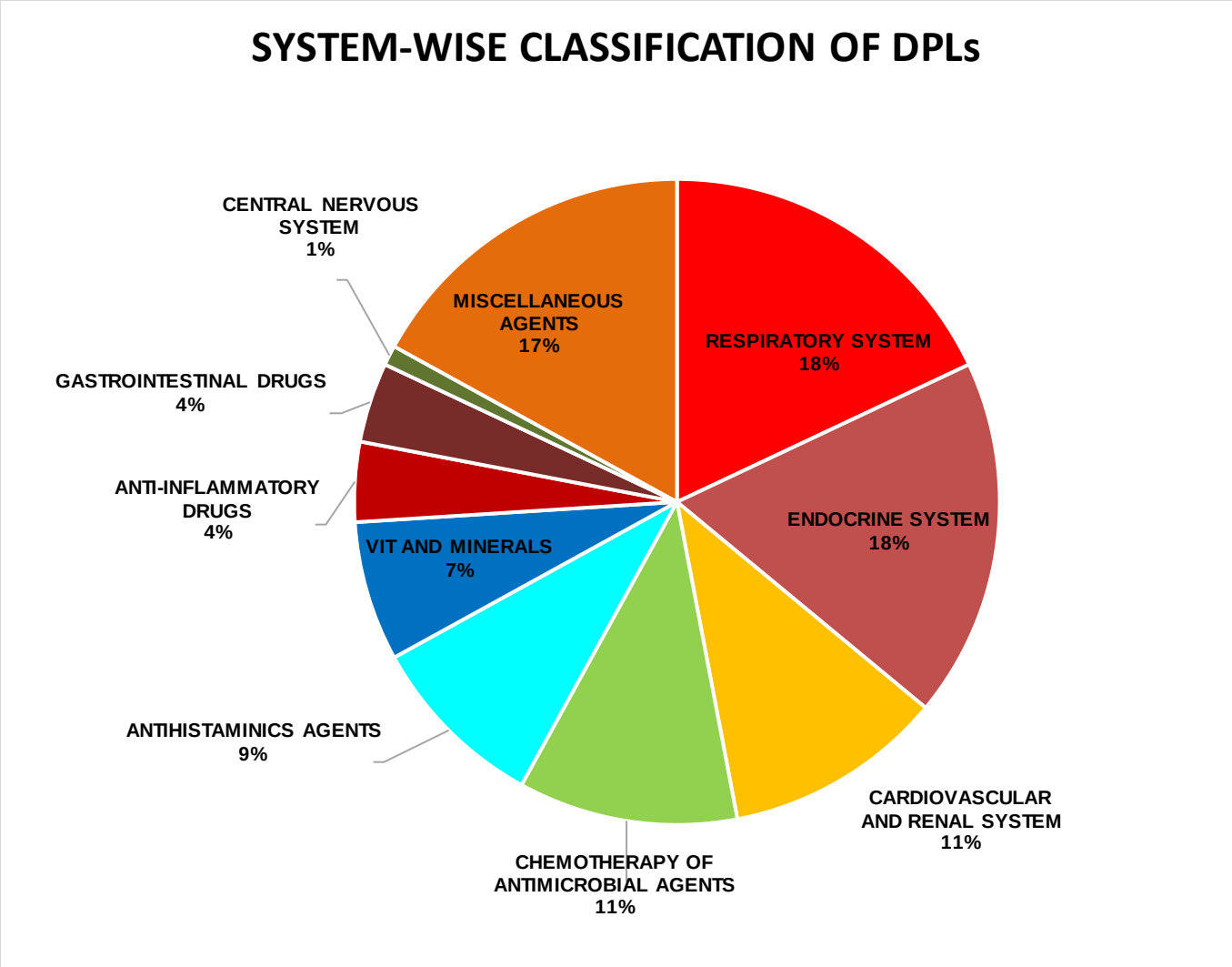

Fig 1:- System-wise classification of DPLs.

Each brochure was analysed according to the "WHO Criteria for Ethical Medicinal Drug Promotion 2015" and "OPPI Code of Pharmaceutical Marketing Practices 2019":

INN and the brand name were mentioned by 100% of DPLs. The amount of active ingredients and approved therapeutic indications were mentioned by (99%) and (96%) respectively. The name of the excipient was the least mentioned criterion 0%. The dosage form or regimen was mentioned by 87% of DPLs. Criteria like side effects, precautions/contraindications, and major interactions were mentioned in 28%, 29%, and 14% respectively. The name and address of the manufacturer were mentioned in 87% of the DPLs. And a total of 77% of DPLs mentioned the references.

Table 1:- Percentage of DPLs following the WHO criteria.

WHO CRITERIA	PERCENTAGE
1.INN OR GENERIC NAME	100%
2.BRAND NAME	100%
3.CONTENTS OF ACTIVE INGRIDIENTS PER DOSAGE FORM/REGIMEN	99%
4.EXCIPIENTS	0%
5.INDICATION	96%
6.DOSAGE FORM/REGIMEN	87%
7.SIDE EFFECTS/ADVERSE DRUG REACTIONS	28%
8.PRECAUTIONS/CONTRAINDICATIONS/WARNINGS	29%
9.DRUG INTERACTIONS	14%
10.NAME AND ADDRESS OF MANUFACTURER	87%
11.REFERENCES	77%

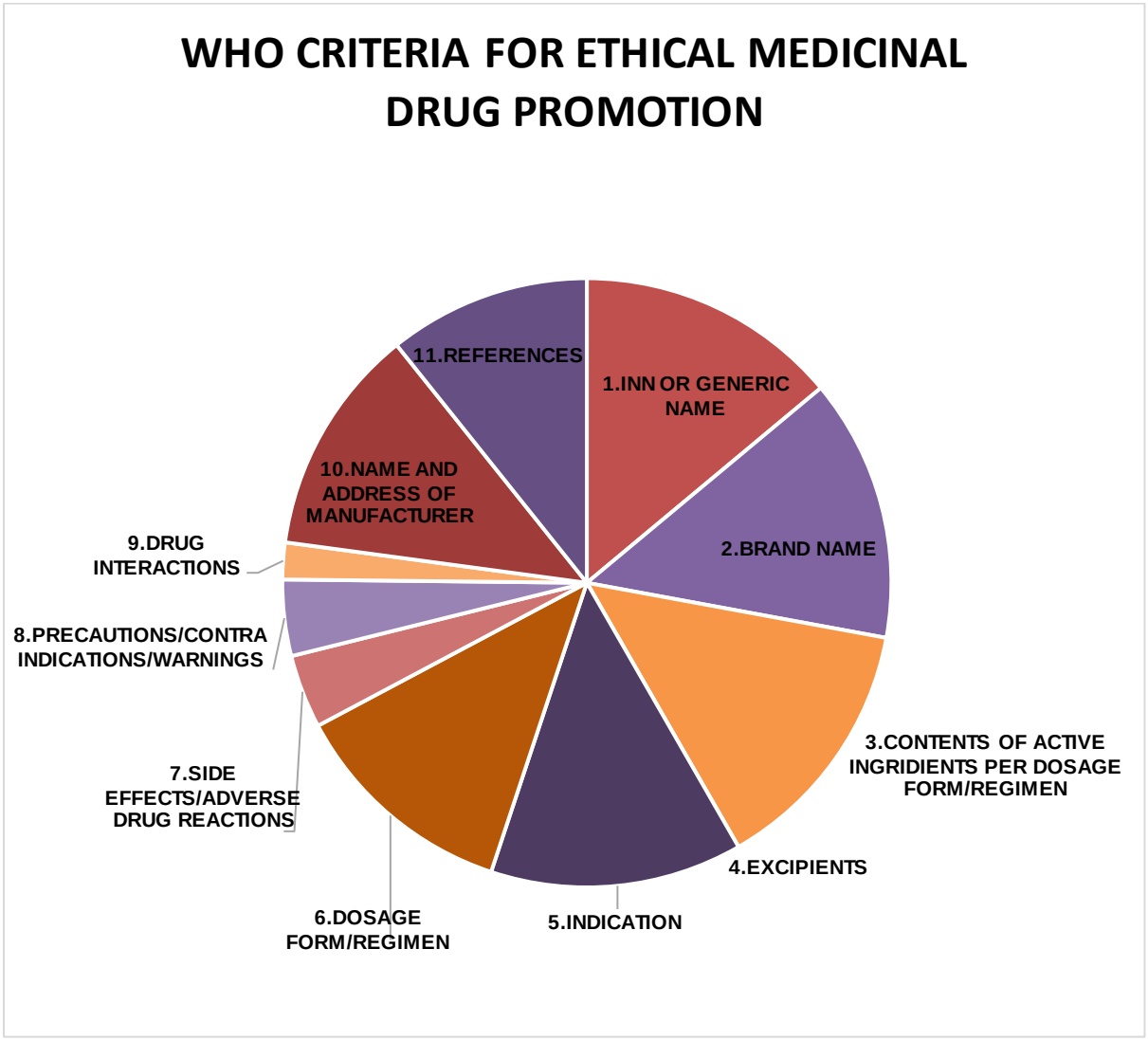

Fig 2:- WHO criteria for ethical medicinal drug promotion.

DPLs were categorised based on these claims wherein 23% were found to be authentic and the remaining 77% were extravagant. Some DPLs were found to have more than one extravagant claim.

CLAIMS	PERCENTAGE
AUTHENTIC	23%
EXAGERRATED	47%
CONTROVERSIAL	26%
MISREPRESENTED	13%
FALSE	5%
AMBIGUOUS	9%

Drug cost was revealed only in 9% of brochures.

Pictures occupied a considerable amount of space on all brochures. Only 39% of DPLs had relevant pictures of drugs being promoted and 61% had irrelevant representation in the form of women, and men occupying major areas. The pharmacological properties were represented in the form of graphs in 17% DPLs. The quality of paper used for DPLs was durable in all the DPLs and the text was legible in 78% of brochures.

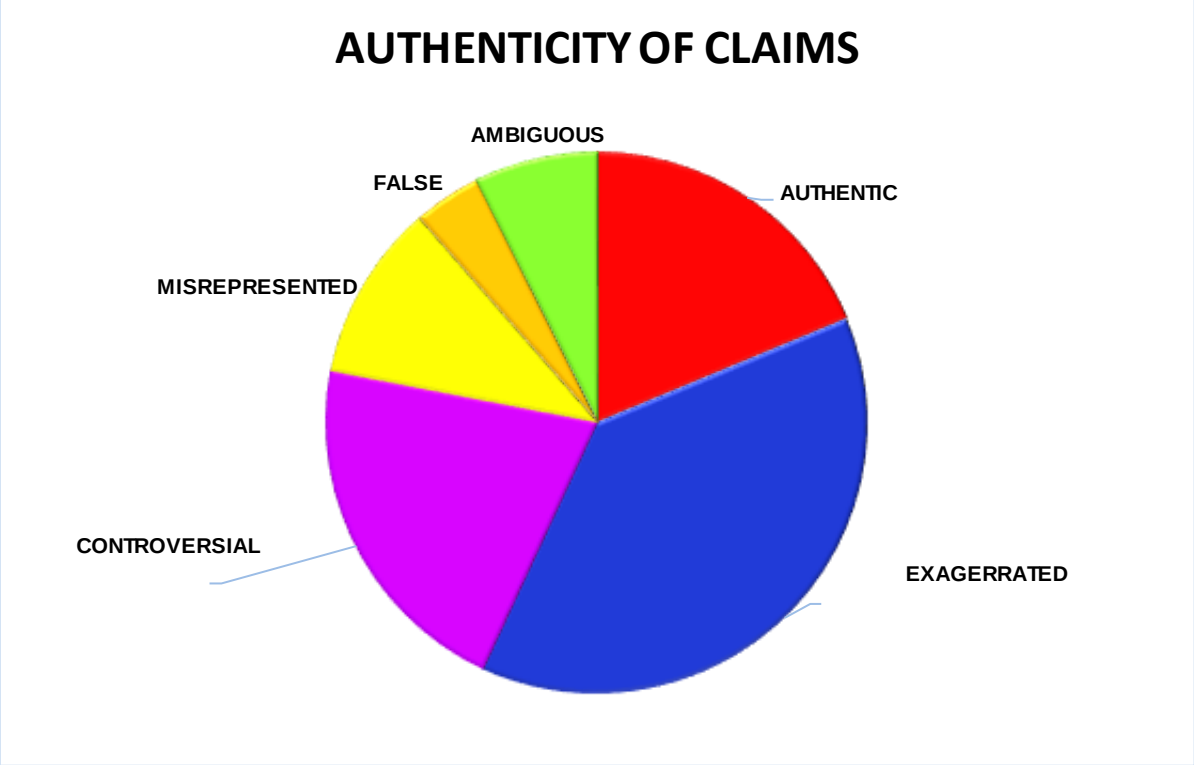

Fig 3:- Authenticity of claims.

Discussion:-

DPL forms a major marketing technique for pharmaceutical companies for propagating information regarding the brand name, its characteristics, cost, claims, and references cited to support these claims. In our study, none of the DPLs followed all the criteria mentioned in the WHO guidelines. We observed that the majority of the DPLs mentioned the generic names, brand names, dosage form/regimen, and approved therapeutic indications but did not stress upon the essential information about ADRs, drug interactions, precautions, and contraindications which were mentioned only about 1/3rd DPLs as seen in other similar studies. Promising unsubstantiated claims, catchy phrases, irrelevant charts, and tables were a part of a significant number of DPLs. Manufacturers' names, addresses and references were mentioned in about ¾th DPLs. The cost of the drug was mentioned in about 9% of DPLs.

A study conducted in 2019 by Dr.Kakode et al showed that only 4% of the 250 DPLs collected had followed 100% of the WHO criteria. The total number of claims were 344 of which 52.8% were authentic and 47.2% were misleading.

Of the misleading claims: 28.7% were exaggerated, 34.7% were controversial, 22.8% were false, and 23% were ambiguous.[12]

Another similar study done by Dr. Mangla et al in the year 2018 showed only 2% of the DPL fulfilled all the WHO criteria and none fulfilled the OPPI Code of Ethical Practice. DPL was highly compliant (≥70%) with respect to the brand name, active ingredients & their contents, manufacturer's name, and address and depicted moderate compliance (40-69%) towards the mention of approved indications and dosages. Regrettably, the majority of DPLs were poorly compliant (≤39%) in terms of the references, side effects, precautions, warnings, contraindications, interactions, and names of other ingredients. The cost was mentioned in only about 4% of the DPLs and the date of production of the advertisement was not mentioned in any of the DPLs. Antibiotics (20%) were the most promoted group of drugs. 65% of the promotional literature was designed for the promotion of FDCs.[13]

In another observational, cross-sectional study at a tertiary care hospital, in Delhi; Dr. Gautam et al in 2017 found that out of the 208 promotional brochures analysed, only 5.8% of the promotional literature fulfilled all the WHO criteria. Nutritional supplements (27.9%) were the most promoted group of drugs. Pharmaceutical companies were most reluctant to provide information regarding contraindications (9.6%), adjuvants (11.5), side effects (10.6%), and drug interactions (9.6%). The generic names, brand names, dosage forms, and therapeutic indications were mentioned in most of the brochures. Exaggerated emotional claims were made in 47.1% of brochures, followed by that of efficacy in 39.4% and safety in 25% of brochures. Pictures of medicinal products outnumbered others with 39.9%, followed by pictures of women, children, and doctors with 20.7%, 17.3%, and 13.5% respectively.[14]

Our study was conducted during the COVID pandemic and as a result respiratory and endocrine drugs were the most commonly promoted drugs followed by cardiovascular and renal drugs, antimicrobials, anti-histaminics, and vitamins and minerals showing that pharmaceutical companies target prevalent conditions in the population.

In our study, we observed that 77% of claims made in the DPL by the pharmaceutical companies were extravagant and about a quarter of the claims were found to be authentic. About 47% of the claims were exaggerated beyond the actual benefit, 26% were controversially and supported by only a very few clinical studies whereas contradictory data was available questioning the validity of these claims,13% were misrepresented to suit the claims, 5% were false and there was no scientific data available to support these claims and 9% were ambiguous and vaguely described.

The information provided in the DPLs cannot be relied upon, moreover, very few physicians are equipped with the skills to critically analyse it. The new drug should be relevant to the physician's practice and it should be preferred over the old drug only when it offers clear benefit in terms of efficacy, safety, tolerability, and cost. Physicians are susceptible to the marketing strategies of pharmaceutical companies who are concerned with the promotion of their products rather than education. About one-third of all sales earnings are spent on promoting the products, which is about double the amount spent on research and development.

Misleading drug advertising encourages drug consumerism rather than the rational use of drugs. There is still an unmet need for the dispersal of unbiased information to the prescribers. Promotional literature continues to be far from educational. There is a need to inculcate the art of critical appraisal amongst doctors, so that they may derive the best from the information made available to them in the form of promotional literature. As the majority of the general practitioners and specialists consider DPLs as their primary source of information regarding drugs, it can be anticipated that inappropriate advertisement would lead to irrational prescribing if the physicians blindly follow these claims. Regional Ethics Committees in various cities in India collect complaints about unethical drug promotion and report them to the Drug Controller General of India to take necessary legal steps to regulate companies to publish DPLs to fulfill the WHO criteria.

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