ISSN 2515-8260 Volume 09, Issue 03, 2022

Evaluation of the rationality of the drug promotional literature distributed among the physicians using the W.H.O guidelines

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ABSTRACT

Background:One of the key elements for the marketing of drugs and especially the new ones that are entering the market undertaken by the various pharmaceuticals industries is the use of drug promotional literature.

Material and Methods:A total of 300 DPLs were assessed for their completeness according to the W.H.O criteria.

Results: A total of 300 DPLs were analysed out of which 66% (198) of the total DPLs promoted a single drug and 34% (102) DPLs were FDCs. Most of the DPLs were related to the drugs acting on the cardiovascular system (17.33%). Upon assessing the DPLs in accordance with the W.H.O criteria it was found that 95.67% (287) DPLs had the International non-proprietary name (INN) mentioned in them while 100% (300) DPLs had the brand name written on them. The active dosage form of the drug was mentioned in 95.67% (287) DPLs. Most of them published the dosage form [98% (294)], name and address of the manufacturer or distributor [97.66% (293)].the excipients were mentioned in only 4.67% (14), precautions and warnings in 42.67% (128), contraindications to the use of medications in 46.33% (139), major drug interactions in 41.67% (125), address of the manufacturer or distributor in 65.33% (196).

Conclusion:The pharmaceutical companies are trying to meet the requirements as laid down by the WHO for drug promotional literature but still some regions remain an area of concern.

Keywords: DPL, WHO ethical criteria, INN

Background & Rationale

One of the key elements for the marketing of drugs and especially the new ones that are entering the market undertaken by the various pharmaceuticals industries is the use of drug promotional literature.[1,2] The W.H.O has very aptly and comprehensively defined the drug promotion as"all informational and persuasive activitiesby manufacturers and distributors, the effect of which is toinduce the prescription, supply, purchase and/or use of medicinaldrug".[3]Most of the pharmaceutical companies promote their drugs in a rather aggressive manner.[4,5] The most common marketing strategy opted by the companies is physician targeted promotion of the products in which the medical representatives play the most vital role.[6,7]

The medical representatives resort to the verbal in office promotion of the drugs on coming in contact with the physicians. Further these presentations are often accompanied by giving out advertising brochures and free samplesalong with other form of promotional

materials.[8,9]Keeping these points in mind and to promote the rational use of drugs W.H.O haslaid down the ethical criteria which needs to be followed by the various pharmaceutical industries during the process of drug promotion.[10]

The overwhelming cost of the development of a new drug which can touch the vicinity of $5billion makes the regulations on drug promotion even more important.[11]There have been numerous studies conducted which show that the drug promotional materials are often biased while giving out the information about their concerned products.[12]

With the ever-changingfield of medical science, it is of utmost importance that the physician should keep themselves updated in relation to the scientific use of the prescribed medications.[13] However, the reality of the situation is that the treating physicians are often handicapped by a lack of time to access the medical literature and thus the availability of impartial drug information becomes a constraint especially in case of developing countries.[14]

India with one of the fastest growing economies of the world is among the top 5 emerging markets for the pharmaceutical industries.[15]Butunfortunately over this part of the world a grey zone has been existentoften due to the lack of standard recommendations which paves the way for the pharmaceutical companies to manipulate their drug promotional literatures.Thus, the proper training of the medical fraternity towards the critical analysis of the unethical drug promotional literatures is the need of the hour.13 The presence of a proper training will ultimately help the future prescribers in understanding the detrimental effects of unethical drug promotion.

The present study aims to understand the rationality of the current drug promotional literatures that are being given to the prescribing physicians by the medical representatives and create an awareness in relation to the reliability, credibility as well as the authenticity of the same.

Materials and Methods

This prospective, observational, and cross-sectional study was conducted at the Department of Pharmacology & Therapeutics, King George's Medical University, Lucknow for a period of 6 months from October 2021 to March 2022. The DPLs were collected in the form of flyers, leaflets and brochures from the various out-patient departments of the University which were available through the medical representatives.

The collected DPLs were assessedto include them in the study. The literature promoting medical devices and equipment, ayurvedic medications, nutritional supplements, reminder lists were excluded from the current study. After exclusion a total of 300 DPLs were assessed for their completeness according to the W.H.O criteria which can be outlined as follows:[16]

1. The names of the active ingredients using eitherinternational non-proprietary names or theapproved generic names of the drug
2. The brand name
3. Content of active ingredient per dosage form orregimen
4. Name of other ingredients known to causeproblems, i.e., adjuvant
5. Approved therapeutic uses
6. Dosage form or regimen
7. Side effects and major adverse drug reaction
8. Precautions, contraindications, and warnings
9. Major interactions
10. Name and address of the manufacturer ordistributor
11. Reference to scientific literature as appropriate.

The collected data was entered into a Microsoft Excel spreadsheet and the results were expressed as percentages.

ISSN 2515-8260 Volume 09, Issue 03, 2022

Results

A total of 300 DPLs were analysed out of which 66% (198) of the total DPLs promoted a single drug and 34% (102) DPLs promoted fixed dose combinations.(Table-1, Figure – 1)

Table 1: Types of DPLs analysed

Total DPLs analysed		
Type of drugs promoted	**Number of DPLs**	**Percentage (%)**
Single Drugs	198	66
FDCs	102	34

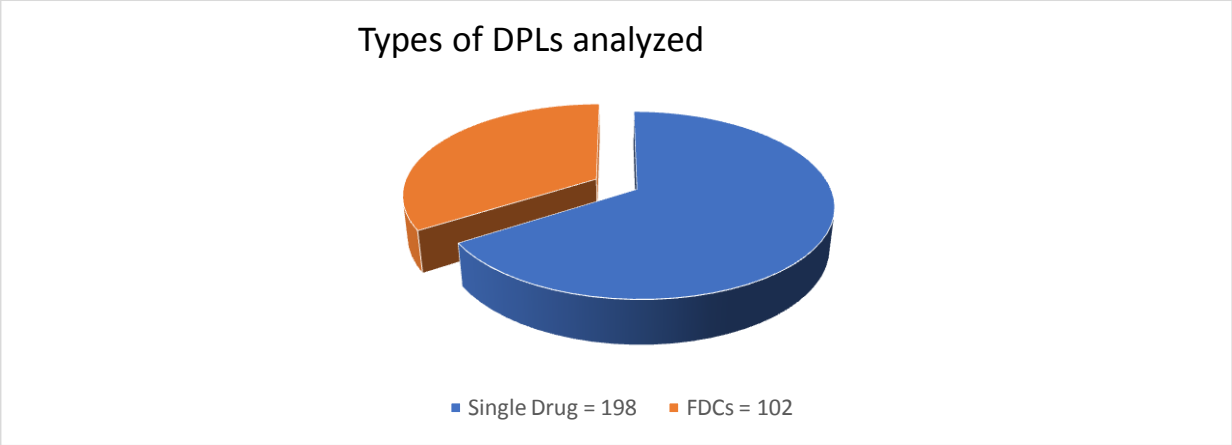

Figure 1: Types of DPLs analysed

Most of the DPLs were related to the drugs acting on the cardiovascular system, i.e: 17.33% of the total literature and hence they were the ones most promoted. The details of the findings are shown in table 2 with the graphical representation of the same in figure 2. Most of these drugs belonged to the ant-hypertensive class of medications. This was followed by oral hypoglycaemic agents and anti-microbials which formed 16% and 13% of the total literature respectively.The NSAIDs and anti-ulcer agents were promoted almost hand in hand with them covering 10.67% and 10.33% respectively.

Table 2: Various classes of drugs advertised through DPLs

Classes of drug advertised	**Number of DPLs**	**Percentage (%)**
Drugs acting on cardiovascular system	52	17.33
Oral hypoglycaemic agents	48	16
Anti-microbials	39	13
NSAIDs	32	10.67
Anti-ulcer agents& Anti-emetics	31	10.33
Miscellaneous	31	10.33
Multivitamins & Minerals	28	9.33
Drugs acting on the respiratory system	24	8
Drugs acting on CNS	15	5

ISSN 2515-8260 Volume 09, Issue 03, 2022

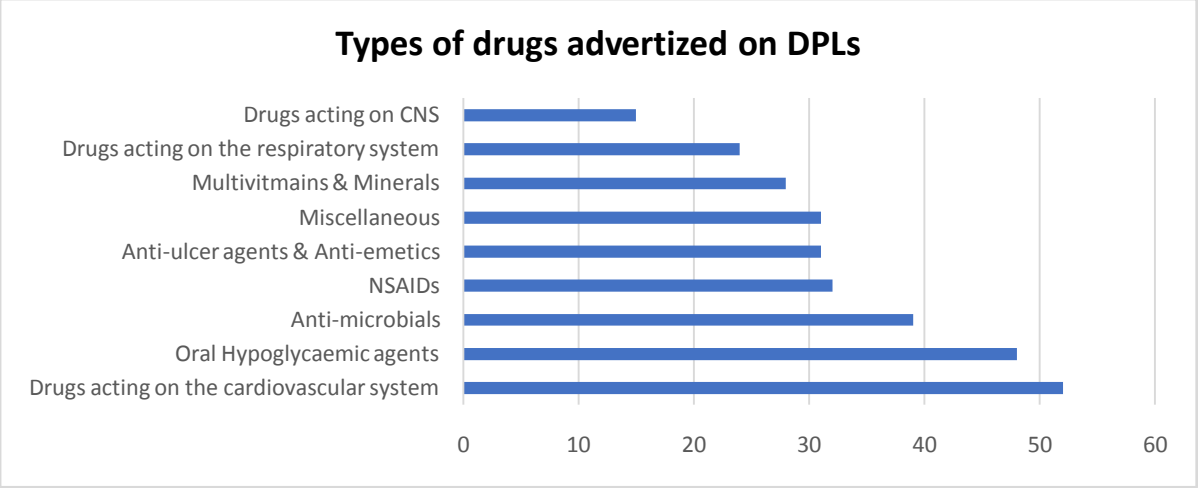

Figure 2: Various classes of drugs advertised on DPLs

Upon assessing the DPLs in accordance with the W.H.O criteria it was found that 95.67% (287) DPLs had the International non-proprietary name (INN) mentioned in them while 100% (300) DPLs had the brand name written on them. The active dosage form of the drug was mentioned in 95.67% (287) DPLs. Most of them published the dosage form [98% (294)], name and address of the manufacturer or distributor [97.66% (293)].

However, the point of concern lies in the fact that the excipients were mentioned in only 4.67% (14), precautions and warnings in 42.67% (128), contraindications to the use of medications in 46.33% (139), major drug interactions in 41.67% (125), address of the manufacturer or distributor in 65.33% (196).

The point of biggest hindrance was found in the observation that 62.67% (188) DPLs only had the appropriate reference to support their claims.

Table 3: Analysis of the drug promotion literature according to W.H.O criteria

W.H.O criteria	Criteria present in	Percentage
INN	287	95.67
Brand Name	300	100
Active drug per dosage form	287	95.67
Other ingredients known to cause problems, i.e: excipients	14	4.67
Approved therapeutic uses	286	95.33
Dosage form	294	98
Dosage regimen	212	70.67
Adverse effects	134	44.67
Precautions & Warnings	128	42.67
Contraindications	139	46.33
Major drug interactions	125	41.67
Name and address of the manufacturer or distributor	293	97.66
Address of the manufacturer or distributor	196	65.33
Reference to appropriate scientific literature	188	62.67

Discussion

The use of concrete scientific, appropriate, and unbiased information is extremely crucial for the physicians in knowing about the new drugs that are being introduced into the market. This information ultimately affects the prescribing behaviour of the treating physician. Hence, the responsibility needs to be borne by the pharmaceutical companies in making a proper DPL that is in accordance with the ethical criteria as laid down by WHO.

In this present study it was observed that majority of the DPLs (66%) were promoting a single drug while 34% of the literature promoted FDCs.

Another point that was seen was that the most promoted drugs were the ones that worked on the cardiovascular system (mostly the anti-hypertensives) followed by the oral hypoglycaemic agents and the anti-microbials.This trend also shows that the patients are now mostly being affected by the metabolic diseases rather than infectious ones. The promotional behaviour may also be representation of the fact that these metabolic diseases are mostly controlled but cannot be treated. The patients thus consume the medications for as long as they are alive making them the more attractive customer base.The promotion of NSAIDs and anti-ulcer agents were seen in 10.67% and 10.33% of the literature. This observation can be a reflection of the common practice of often prescribing them together by the physicians.

During this study it was also found that while the pharmaceutical companies concentrated on providing brand name (100%), INN (95.67%),active drug per dosage form (95.67%), approved therapeutic uses (95.33%), dosage form (98%), name and address of the manufacturer (97.66%). However,the points like excipients (4.67%), dosage regimen (70.67%), adverse effects (44.67%), precautions and warnings (42.67%), contraindications (46.33%), major drug interactions (41.67%) and reference to appropriate scientific literature (62.67%) took a back seat. Similar findings have been reported in many studies.[17,18,19]

Conclusion

From the study that has been conducted it van be derived that the pharmaceutical companies are trying to meet the requirements as laid down by the WHO for drug promotional literature but still some regions remain an area of concern. As the DPLs constitute an important source of information for the physicianwho already has shortage of time in his rather busy schedule about the new drugs that are entering the market, they need to be stringently regulated. The dissemination of concrete, proper and authentic scientific claims need to be encouraged which should be backed up by proper scientific data.

Limitations

This study suffers from the limitation of a small sample size when compared to the drugs that are currently in market. The conduction of the study only in a single centre may not be a proper representation of the entire market.

Author's Contribution: All the authors contributed equally in this study.
Financial support and sponsorship: Nil
Conflict of Interest: There are no conflicts of interest.

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