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Original Article

Evaluation of Adherence of Drug Promotional Literatures (DPLs) to World Health Organization Guidelines

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Abstract :

There is limited mechanism to monitor the drug promotional campaign by pharmaceutical industries despite the fact that there is enough evidence of irrational pharmacotherapy increasingly encountered even in the developed countries. Unethical pharmaceutical promotional practice is a common cause of irrational pharmacotherapy which is a most common problem worldwide. Main objective of this study was to evaluate the medicinal promotional literatures provided by the pharmaceutical companies for accuracy, consistency and validity of the information presented in it, using World Health Organization (WHO) criteria for ethical medicinal drug promotion. Two hundred & fifty (n=250) literatures were collected randomly from selected doctors chambers in Barisal, Bangladesh. One hundred & thirty (130) of those literatures were excluded for being either duplicates, reminder literatures, promoting medical devices or cosmetics. The remaining (120) literatures were then screened to match their macro-informational contents against same advised in world health organization ethical criteria for medicinal drug promotion. The name of active constituent(s), content of active ingredient(s) per dosage form & brand name, were mentioned in 100% (n = 120) of promotional literatures, whereas dosage form were mentioned in 91.66% (n = 110), therapeutic indications were mentioned in 99.1% (n = 119) of literatures but informations on side effects mentioned in only 55.33% (n = 70), contraindications in 63.33 % (n = 76), precautions in 51.67% (n = 62) & references in 70 % (n = 84) of drug promotional literatures (DPLs). None of them mention anything about adjuvant. None of the promotional literatures fulfilled all the WHO criteria. Screened literatures were found to display poorly reliable and unbalanced medication information. Healthcare providers shall, accordingly, seek independent medicinal information sources, and not solely depend on commercial sources of medicinal information. Official regulators shall strictly define and mandate medication information contents in printed pharmaceutical promotional materials. Healthcare providers should, also, master the skills of appraising such promotional printed materials if rational medication use is to be achieved. Pharmaceutical industries did not follow the WHO guidelines while promoting their products, thus aiming to satisfying their commercial motive rather than fulfilling the educational aspect of promotion.

Key words: Medicinal promotional literatures, ethical drug promotion, WHO guideline.

Introduction :

Drug promotion is an integral part of pharmaceutical marketing. These are accepted in health care system through health care professionals. In drug advertisements pharmaceutical manufacturers have an opportunity to proclaim the existence of a drug, promote its advantages, and also provide useful information to help a doctor decide whether & when to use the drug[1]. The World Health Organization defines drug promotion as all the informational and persuasive activities by manufacturers & distributors, the effects of which influence the prescription, supply, purchase and/or use of medicinal drugs[2]. Drug promotion and marketing make up a very large part of the activities of pharmaceutical companies. By using various methods pharmaceutical companies promote their drugs. The most common methods are drug promotion by using medical representatives (MR), distributing free samples, and advertisement through pamphlets, radio, TV & sponsoring medical events[3]. One of the well-known promotional activities of pharmaceutical industries is to produce advertising literatures; companies usually use the written material supposedly showing all the good and bad aspects about the concerned drug[4]. These advertisements can be highly informative as long as they are critically appraised which at times are inaccurate and of poor educational value. These promotional activities create the potential for inappropriate prescribing practices by influencing physicians' prescribing behavior without necessarily

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benefiting the patients but contribute to increased health care costs[5]. The use of gifts, including pens, mugs embossed with pharmaceutical product names, has been prohibited by PHARMA ethics guidelines since 2008. In the booming pharmaceutical market with competitive and aggressive drug promotion by pharmaceutical companies there is every possibility of the promotion being unethical[6]. At the same time, the information provided by the sales representatives is the only source of information about the medicine in developing countries. The reality at present is that most health professionals get their information from commercial sources, usually through an extensive network of medical representative. Moreover, evidence suggests that promotion affects attitudes and behaviour.

Internationally, two sets of guidelines have been developed for pharmaceutical advertising. In 1988, the World Health Organization established the ethical criteria for medicinal drug promotion[7]. These criteria constitute general principles for ethical standard that can be adapted by government to national circumstances. The International Federation of Pharmaceutical Manufacturers Association has adopted a Code of Pharmaceutical Marketing Practices, supplemented by member association & company codes that sets standards for the ethical promotion of medicine[8]. It is a requirement of IFPMA membership that member associations adopt codes that meet local requirements but consistent with, and comprehensive as, the IFPMA Code.

It was observed that unbiased & current drug references were not available in most clinical facilities for healthcare professionals & committees to develop drug lists & for making procurement decisions. There is no mandatory law that regulates the contents of the promotional materials provided by the pharmaceutical companies. Hence we decided to evaluate the rationality of promotional drug literatures as per "World Health Organization criteria for ethical medicinal drug promotion, 1988" which is supposed to regulate the promotional activity of pharmaceutical industries. As the promotional materials provided by the manufacturers can largely influence the clinicians, intervention are needed to improve the content of the promotional materials by the government. Another strategy to overcome the unethical promotional practice is the inclusion of critical analysis of advertisements & other promotional materials against WHO ethical criteria for medicinal drug promotion in the undergraduate curriculum to sensitize the future prescribers regarding rational pharmacotherapy. So the present study was undertaken to evaluate the medicinal promotional literatures by the pharmaceuticals.

Materials & methods:

This study was conducted to find out the accuracy and ethical status of promotional drug literature presented to prescribers by using "WHO criteria for ethical medicinal drug promotion, 1988". This study was conducted by collecting two hundred & fifty drug promotional literatures (n=250) randomly from different doctors chambers in Barisal, Bangladesh, over the period of I5 days from 1st April, 2015 to 15th April, 2015. Some literatures were presented along with the reprint of journal article quoted in it as a reference to the information. Collected literatures were then explored to exclude the following materials: Literature promoting medicinal devices and equipments (insulin pump, blood glucometer, etc.), orthopedic prosthesis and ayurvedic medicines, drug monographs, reminder advertisements (reminder advertisements do not present any therapeutic information and have different criteria for evaluation), drugs name list, and literature promoting more than four brands. Thus one hundred & thirty (130) of those literatures were excluded & the remaining one hundred twenty literatures were then screened to match their macro-informational contents against same advised in world health organization ethical criteria for medicinal drug promotion.

WHO criteria for ethical medicinal drug promotion dictate that promotional literature should contain following information:

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;
8. Precautions, contraindications and warnings;
9. Major drug interactions;
10. Name and address of manufacturer or distributor;
11. Reference to scientific literature as appropriate.

Result:

One hundred & twenty drug promotional literatures were evaluated from twenty five different manufacturers. A total of 68 drugs were promoted in those 120 drug promotional literatures. Among those drugs 30.83 % were chemotherapeutics, 19.16 % were used in cardiovascular diseases, 6.66 % used in respiratory disease, 2.5 % were Antidiabetic, 4.16 % were used in CNS diseases, 10.83 % used in diseases affecting GIT. Different drug groups those included in the drug promotional literatures of this study were showed in Table I.

Table I: Therapeutic category of drugs promoted in promotional literatures (n = 120)

Drug group	Total no of Literatures (n=120) (%)
Chemotherapeutics	37 (30.84)
CVS drugs	23 (19.17)
Respiratory drugs	8 (6.66)
Antidiabetic drugs	3 (2.50)
CNS drugs	5 (4.16)
Steroids	4 (3.34)
Vitamins & minerals	11 (9.17)
NSAIDs	8 (6.66)
GIT drugs	13 (10.84)
Antihistamines	8 (6.66)

Analysis of general pharmaceutical information according to WHO specification presented in the promotional literatures was showed in Table II & Table III.

Table II: Evaluation of promotional literatures as per WHO criteria (n=120)

WHO criteria	Mentioned number (%)
Generic name	120 (100 %)
Brand name	120 (100 %)
Content	120 (100 %)
Adjuvant	0 (0 %)
Dosage form	110 (91.67 %)
Indications	119 (99.17 %)
Side effects & adverse reactions	70 (58.33 %)
Contraindications	76 (63.33 %)
Precaution & warning	62 (51.67 %)
Major interactions	12 (10 %)
Name and address of manufacturer or distributor	120 (100 %)
References	84 (70 %)

Table III: Availability of general informations included in the drug promotional literatures according to WHO ethical criteria (n=120)

Drug Group (n=120)	G(%)	B(%)	C(%)	A(%)	DF(%)	I(%)	S(%)	CI(%)	P(%)	MI(%)	MN	R(%)
Chemo-therapeutics (37)	100	100	100	0	83.78	100	40.54	40.54	35.14	10	100	75.68
CVS drugs (23)	100	100	100	0	91.30	100	43.48	56.52	52.17	00	100	69.57
Respiratory drugs (8)	100	100	100	0	100	100	100	87.5	75	00	100	87.5
Antidiabetic drugs (3)	100	100	100	0	100	100	66.67	66.67	66.67	00	100	100
CNS drugs (5)	100	100	100	0	100	100	0	20	20	00	100	80
Steroids (4)	100	100	100	0	100	100	25	50	50	00	100	50
Vitamines & minerals (11)	100	100	100	0	100	100	90.91	90.91	54.55	00	100	54.55
NSAIDs (9)	100	100	100	0	88.89	88.89	88.89	66.67	55.56	00	100	77.78
GIT drugs (13)	100	100	100	0	92.31	100	84.62	92.31	84.62	00	100	61.54
Anti-histamines (7)	100	100	100	0	100	100	71.43	85.71`	57.14	00	100	42.86

NB: G=generic name, B=brand name, C=content of active ingredient(s) per dosage form, A=adjuvant, DF=dosage form(s), I=indication(s), S=side effects & adverse reaction(s), CI=contraindication, P= precaution & warning, MI=major interaction(s), MN=name & address of manufacturer or distributor, R=reference of scientific literature as appropriate

Table II & Table III showing that the name of active ingredient, brand name, content of active ingredient per dosage form, name & address of manufacturer or distributor mentioned in 100 % (n=120) DPL, other criteria like dosage form mentioned in 91.67% (n=110), indication in 99.17% (n=119), side effect & adverse effect in 58.33% (n=70), contraindication in 63.33% (n=76), precaution & warning in 51.67% (n=62), major interactions in 10% (n=12), reference in 70% (n=84) of DPL, but out of 120 DPL, none of them mentioned anything about adjuvant used in those dosage formulations which can cause problem.

Discussion:

In this study, chemotherapeutic agents were the most promoted group (30.84%), and they can contribute to development of drug resistance due to overuses. Cardiovascular drugs (19.17%) and drugs used in GIT disorders (10.84%) come close second and third among promoted drugs in 120 studied literatures.

In our study, out of 120 drug promotional literatures, the name of active constituent(s), content of active ingredient(s) per dosage form, brand name, manufacturers name were mentioned in 100% (n=120) of DPL, whereas dosage form were mentioned in 91.66% (n=110), therapeutic indications were mentioned in 99.1% (n=119) of literatures but informations on side effects [55.33% (n=70)], contraindications [63.33% (n=76)], precautions [51.67% (n=62)], major interactions [10% (n=12)] mentioned in those medicinal promotional literatures were not satisfactory. After excluding lowest presented criteria, i.e. adjuvant, rest ten criteria were fulfilled by only 30.83% (n=37) literatures. Total 120 drugs promotional literatures were screened & none of them fulfilled all WHO criteria.

Previous such study in our country showed that out of total 83 DPLs, 96.2 % mentioned the generic name, indications in 81.5%, contraindications in 50%, adverse effects in 29.7%, content in 64.8%, precaution in 37%, but information about adjuvant was missing in all screened DPLs[9].

In 2009, a study was conducted in Nepal showed that out of total 33 DPLs, the name of active constituent(s) were mentioned in 87.87% (n=29), dosage form & manufacturers name in 90.90% (n=30), indications in 87.88% (n=29), side effects in 33.33% (n=11), precautions & contraindications in 36.36% (n=12) DPLs[6].

Another such study conducted in India, in 2014, showed that out of total 437 DPLs, generic name, brand name, dosage form, indications, manufacturers name, content, adverse drug reactions & precautions were mentioned in 98%, 100%, 100%, 97%, 100%, 82% & >90% of DPLs respectively[10].

A similar study conducted in India, in 2010, showed that out of 513 DPLs, generic name, brand name, content, indications, dosage form, safety in formations (side effects, contraindications, precautions), manufacturers address, references were outlined in 95.9%, 100%, 79.5%, 86.3%, 87.1%, 8.8%, 70.6%, 61.6 % respectively[11].

In 2014, another such study conducted in India in which 200 DPLs were screened. In that study, informations on adverse drug reactions, contraindications, & drug interactions were missing in most of the DPLs & none of the DPLs contained all of the information as per WHO guidelines for medicinal drug promotion[12].

Findings of our study & that of other studies done our country & in Nepal & India showed that pharmaceutical industries were most reluctant to provide information regarding adverse effects, precautions, drug interactions and adjuvant, rather promotion was only focused on latest drug formulations.

Conclusion:

From this study it was concluded that pharmaceutical industries did not properly follow the WHO guidelines during their drug promoting activities, thus accelerated their commercial motive rather than ethical educational aspects. As printed promotional material is an important source of information. The information provided for drug promotion should be accurate, scientific, and evidence-based to keep the doctors informed about the company's products and all related information. On the basis of the observations of this study, it is suggested that physicians need to be aware of the flaws in promotional literature before accepting it as valid information. This could help monitor it with great vigilance. This study evaluates one type of promotional activity of pharmaceutical company, i.e. printed promotional literature; however, interventional research to assess the awareness of the physicians about these facts and alerting them about the same will help gain accurate and ethical information from promotional literature.

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