Research Article

Drug promotional literatures: Educative or misleading for young medical graduates and students?

Abdullahi Rabiu Abubakar, Shabbir Ahmad Sheikh, Mainul Haque

Faculty of Medicine (FP), Universiti Sultan Zainal Abidin (UniSZA), Kuala Terengganu, Terengganu, Malaysia.

Correspondence to: Mainul Haque, E-mail: runurono@gmail.com

Received May 12, 2015. Accepted May 23, 2015

Abstract

Background: Drug promotion (DP) in hospitals is growing considerably. High level of competition exists among pharmaceutical companies in the quest for the prescription. However, a large number of medical representatives promote their drugs in an unethical way, which may pose challenges to the physicians for the rational selection of drug, especially young graduates and medical students. DP is carried out mainly through the use of drug promotional literatures (DPLs), which if not regulated may cause harm to the patient and enormous loss of resources from the wrong choice of medication, drug interactions, or adverse drug reactions (ADRs) due to inadequate or misleading information. **Aims and Objective:** This study aimed at evaluating the DPLs based on as per WHO criteria 1988. **Materials and Methods:** A total of 235 DPLs were collected from different public and private hospitals of Kuala Terengganu, Malaysia. One hundred and forty DLPs that met the inclusion criteria were evaluated according to WHO criteria. **Result:** Among the 140 DPLs, 58.6% presented single-dose medications and 41.4% presented fixed-dose combinations. However, only 49.3% literatures stated the side effects and major ADRs; only 45% gave precaution, contraindications, and warnings, and only 25% provided the major interactions. In addition, 32.9% literatures made the false claim and catchy statement and 40.7% presented irrelevant pictures. In contrast, 55.7% showed relevant charts and 52.1% had relevant tables. **Conclusion:** The research finding has shown that none of the DPLs has fulfilled the WHO criteria. They also contain false claim and catchy statement. Henceforth, drug regulatory agencies must work proactively to ensure compliance by drug companies. Therefore, both physicians and medical students require skills on how to evaluate DPLs.

KEY WORDS: Drug Promotional Literatures; Pharmaceutical Companies; Medical Representatives; Prescribers; Information

Introduction

Drug promotional materials (DPLs) are used by pharmaceutical companies (PCs) to promote their existing or newly marketed drugs to the prescribers.[1–3] However, a large number of DPLs used by these PCs did not meet the World Health Organization (WHO) 1988 criteria for DPLs.[3–6] It was established that the DPLs presented to the physicians has the significant impact on their prescription pattern.[5,6] Similarly, research has shown that the information contained in the majority of DPLs is usually unsatisfactory, fascinating, and biased.[2,3,5–8] Majority of DPLs comprise irrelevant pictures, tables, and charts, which may have a negative influence on the prescribers' decision-making.[1,3,4] It was revealed that most of the PCs failed to conduct or present post-marketing studies on safety and efficacy on DPLs to back up their claim.[5,8] Similarly, symbols and unnecessary abbreviations are frequently used on DPLs, which may be misinterpreted by physicians and consequently affect the quality of patient care.[1,9] Metaphors

Access this article online	
Website: http://www.njppp.com	Quick Response Code:
DOI: 10.5455/njppp.2015.5.1205201548	

and catchy statements are regular to attract the attention of physicians to rush into recommending their products.[9] A statement is considered as 'catchy' if the language used is not clinically feasible or its primary reason is to attar the mind of the prescriber or it is solely for advertisement purpose rather than what is obtainable in clinical practice. Example drug is a total cure; the drug has the fastest action, or the drug is user-friendly.[10]

Ideally DPLs should contain safety information such as contraindications, precautions, warnings, side effects, use of drugs in special cases such as pregnant and lactating mothers, children, and elderly patients. Unfortunately, PCs usually withheld such vital information.[2,8] Recent study has shown that a lot of risks are associated with the use of drugs on these categories of patients.[11] According to WHO, DPLs should provide genuine, reliable, and satisfactory information consistent with scientific literatures to the prescribers.[1,8,9] However, research conducted indicated that DPLs have contributed to irrational drug use, leading to overprescription, self-medication, drug misuse, and drug abuse.[1,4,8,12]

PCs are recognized by WHO as business ventures.[1] However, drug sales and promotion should be done according to the ethics.[6,8] It was established that PCs make unethical drug promotion (DP) through unprofessional sales representatives, which may lead to the false claim and negatively affect healthcare delivery services.[1,12] Consequently, this behavior contributes to medication error.[13] The primary aim of PCs is to convince the physicians that their drug product is superior to others even without scientific proof, and perhaps the drug is of inferior or no efficacy at all.[3,4,7] PCs are also expected to comply with ethical guidelines of International Federation of Pharmaceutical Manufacturers Association in promoting their product.[3,4,6] At present, PCs have broadened their quest for prescribers by distributing free drug samples, eye-catching brochures, and gifts, and sponsoring some prescribers for conference and continued medical education to win prescription.[1,3,7] Owing to their busy schedule, a large number of physicians rely on DPLs as a source of information.[7,9] It is important to note that WHO in 1988 provided the guidelines on DPLs to be used in its member states.[3,7] Unfortunately, many countries are yet to apply them effectively.[12]

The presence of drug sample on physician desk has a significant influence on prescriber's choice of medication.[14–17] A survey conducted reported that PCs have distributed drug samples worth US$7 billion in 1999.[14] In the USA, PCs distributed drug sample amounting to the huge sum of money (US$14 billion) for DP.[14] Similarly, DP has resulted in higher prescription calcium channel blockers than other more effective antihypertensive.[14,16] Doctors that claimed to rely on scientific data rather than commercial source for information on drug efficacy have been prescribing propoxyphene and centrally acting vasodilators despite the availability of clinical literature indicating lack of efficacy, and perhaps token gifts and drug samples given to them are the cause.[14,16] This type of behavior is believed to have a negative effect and perhaps cause waste of resources by patient and nation.[14,16] However, in an attempt to control the issue, policy-makers have launched No Free Lunch website (www.nofreelunch.org). Through this site, names of doctors that said no to free lunch, money, or sponsorship by PCs are published.[14] PCs distribute eye-catching DPLs and token gifts to the prescribers, which have a disruptive influence on prescribers' selection of medication.[15–19] PCs increase promotion of expensive drugs to get more profit and prevent drug expiries.[18] Because of these and many other reasons PCs contribute to prescription-related problems.[14–19] In general, DPs have caused increase in expenditure of government-owned and private PCs to US$3.07 in Australia and US$ 15.7 in the USA, which has raised the burden on government and public taxation.[15,17–21] It is imperative to note that DPLs apart from DP also promote diseases just to attract more prescription.[18] Medical students need to learn good prescription skills, interpretation of DPLs, and other sources of drug information before graduation.[20,22,23] The pattern of prescription by doctors depends on the training they had during their clinical practice.[20,22,23] Recent curriculum update included self-directed learning skills, which will perhaps aid interpretation of DPLs by medical students in the future.[20,22,23] Malaysian medical students curriculum is integrated, which comprises preclinical courses and clinical courses,[24,25] but to best of our knowledge working as medical lecturer for number of years, we still have no information whether any medical school in Malaysia has incorporated program to develop skills to interpret DPLs. The purpose of this research was to appraise the DPLs based on their scientific and ethical status using WHO criteria 1988. Other aims were to assess whether DPLs contain all necessary information, especially regarding adverse drug reactions (ADRs) as these often remain in a physician's table and read by them, and to compare the references used in DPLs.

Definition

DP can be described as "all the information and persuasive actions of manufacturers and distributors, the effects of which is to induce prescription, supply, purchase, and or use of medicinal drugs".[1–4,10]

Materials and Methods

The research is an observational and cross-sectional study. The DPLs were collected from different public and private hospitals of Kuala Terengganu, Malaysia, while doctors were disposing and cleaning their office or chambers. A total of 235 DPLs were obtained within the period of September to November 2014. The DPLs comprised of literatures advertising drugs, medical devices and equipment, promotion on surgical procedures, and new research findings.

Inclusion and Exclusion Criteria

Only literatures are written in English and those used for DP were included. Literatures written in Malay and those that are not for DP were excluded. Out of 235 DPLs, only 140 met these

criteria. A total of 140 DPLs were evaluated according to WHO 1988 criteria for fulfillment of the parameters. The DPLs were collected from local hospitals in Kuala Terengganu, Malaysia. Therefore, the majority of them were written in local Malay language. Henceforth, it was difficult to read and interpret by the authors as they are expatriates.[3,7,10] The parameters are:

1. The name(s) of the active ingredient(s) using either international non-proprietary names or the approved generic name of the drug
2. The brand name
3. Single drug (SD) or fixed dose combination (FDC)
4. Content of active ingredient(s) per dosage form or regimen
5. Approved therapeutic uses
6. Dosage form or regimen
7. Side effects and major ADRs
8. Precautions, contraindications, and warnings
9. Major interactions
10. Name and address of manufacturer or distributor
11. Reference to the scientific literature as appropriate
12. The references mentioned in the literatures were evaluated for authenticity.

Results

Among the 140 DPLs evaluated, 135 (96.4%) provided generic name and 138 (98.6%) mentioned the brand name (Table 1). Similarly, 82 (58.6%) were SDs formulation and 58 (41.4%) FDCs (Figure 1; Table 1). Only 89 (63.6%) DPLs described dosage regime. Again 112 (80%) of the research DPLs contained an address of the manufacturer.

The classes of drug presented were antiasthma (ATAS) (3.5%), antiulcer (ATUC) (3.3%), antiemetic (ATEM) (3.4%), antiscar (ATSC) (3.0%), anticoagulants (ATCG) (3.3%), antidiabetic (ATDB) (2.9%), antiplatelet (ATPL) (2.7%), eye preparations (EPR) (2.9%), pregnancy inducers (PGID) (2.8%), contraceptives (CRTP) (3.6%), antifungal (ANTF) (3.6%), herbal (HEB) (4.3%), analgesic (ANGS) (5.7%), antibiotics (ANTB) (6.4%), hormonal replacement therapy (HRT) (10%), antihypertensive (ANTH) (10%), nutritional supplement (NTRSP) (15.7%), and others (OTHR) (12.9%) (Figure 2).

Safety Information

Among the DPLs assessed, only 69 (49.3%) stated the drug side effects and major ADRs; only 63 (45%) gave precaution, contraindications, and warnings; and only 35 (25%) provided the major interactions (Table 2). Majority of DPLs 119 (85%) did not present any study to back up their claim. In addition, 46 (32.9%) made false claim and catchy statement. Also, 57 (40.7%) presented irrelevant pictures. In contrast, 78 (55.7%) showed relevant charts, and 73 (52.1%) had relevant tables (Table 1).

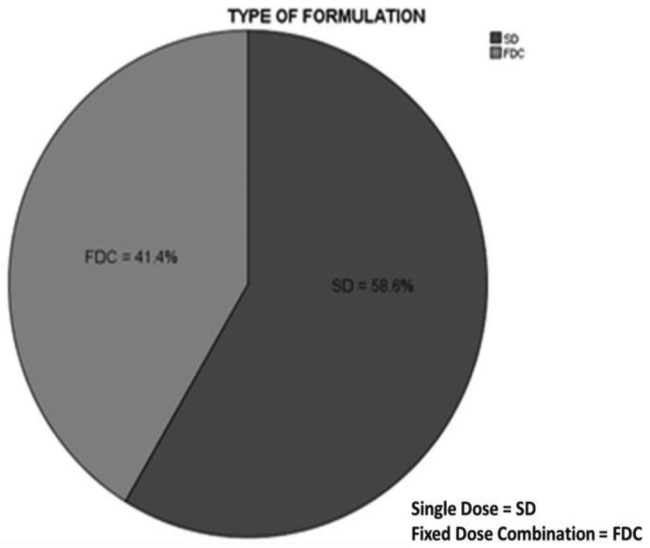

Figure 1: Types of the formulations presented in drug promotional literatures.

Table 1: Frequency and percentage of WHO parameters in drug promotional literatures

Items		Frequency (%)
Generic name		135 (96.4)
Brand name		138 (98.6)
Type of formulation	Single dose	82 (58.6)
	Fixed dose combination	58 (41.4)
Dosage		89 (63.6)
Address		112 (80)
Study conducted		21 (15)
Catchy statement		46 (32.9)
Chart	Relevant	78 (55.7)
	Irrelevant	2 (1.4)
Tables	Relevant	73 (52.1)
	Irrelevant	7 (5)
Pictures	Relevant	50 (35.7)
	Irrelevant	57 (40.7)

References

The DPLs presented different type of references including journals 104 (74.3%), data on file 18 (12.9%), website 15 (10.7%), report 20 (14.3%), book 16 (11.4%), and prescription information 26 (18.6%) (Table 3).

Discussion

The result of this study indicated that all the DPLs analyzed either did not meet the WHO 1988 criteria for DPLs or violated it by adding false claim, catchy statement, or unnecessary materials.[10] Similar findings were obtained by various

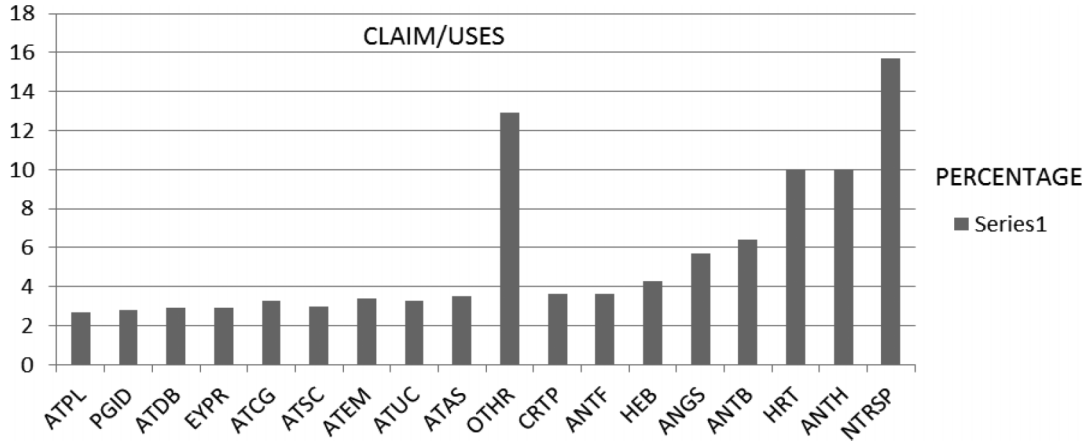

Figure 2: Classes of the drugs presented in drug promotional literatures.

Table 2: Drug safety profile presented in drug promotional literatures

Serial number	Safety information	Frequency (%)
1.	Side effects and major ADRs	69 (49.3)
2.	Precautions and contraindications	63 (45)
3.	Major interactions	35 (25)

Table 3: References provided by drug promotional literatures

Serial number	References	Frequency (%)
1.	Journal	104 (74)
2.	Data on file	18 (12.9)
3.	Website	15 (10.7)
4.	Report	20 (14.3)
5.	Book	16 (11.4)
6.	Prescription information	26 (18.6)

studies.[3,4,7] The DPLs consisted of SD formulations (58.6%) and FDCs (41.4%), which is similar to the outcome of other studies.[3,4,6] It was observed that several DPLs withheld the safety information as only 49.3% presented side effects and major interactions, 45% precaution, contraindication and warnings, and 25% major interactions, which are similar to the results obtained by other researchers.[2,6,26] Similarly, 36.4% DPLs did not state the dosage regiment, 20% did not give the manufacturers' address, and 85% did not conduct any study to back up their claim. The comparable outcome was established in other researches.[6,8] It is indispensable for PCs to conduct post-marketing study on safety and efficacy to justify their claim. In addition, 32.9% made a catchy statement and false claim, which may mislead the prescriber from recommending the right medication and this is similar to outcome of other studies.[12] It has become necessary for regulatory authorities to ensure that PCs comply with WHO 1988 criteria for DPLs. Among the DPLs evaluated, 1.4% presented irrelevant charts, 5% presented irrelevant tables, and 40.7% presented irrelevant pictures, which may distract the attention of the reader from the vital information. This is proportional to the result found in another study.[6] It is essential for a physician to assess the quality of the information provided by the DPLs. In this study, the sources of information provided were journals (74.3%), data on file (12.9%), website (10.7%), report (14.3%), book (11.4%), and prescription information (18.6%), which were similar to many research findings.[3,4,6,7] The way forward is for PCs to engage in clinical presentations and organized lectures in hospitals and also among community pharmacist. Survey reported that among the DPLs studied 44% of them could lead to irrational prescribing, 60% contain image that could distract mind from the drug ADRs; this could perhaps be confirmed as 80% of them made unsupported claims.[18,21] Regulatory authorities should control the size of gifts, educational sponsorship, and other supports given to prescribers by PCs to reduce bias.[15–17] Policy-makers have a role to play in supporting rational DP; PCs that promoted high-quality drugs and whose DPLs meet the WHO criteria should be given special incentives. This will prevent companies making an unnecessary claims to maximize sales and profit.

Limitation of the Study

This research covers few DPLs from Kuala Terengganu public and private hospitals. Also, it does not cover other items promoted in hospitals such as medical devices and equipment, surgical procedures, and new research findings. Although the WHO criteria for DPLs are expected to be applicable globally, the basic requirements may vary from one country to another.

Conclusions

The information provided by DPLs consists of many irregularities; it is partial by concentrating mainly positive aspect of the drug therapy while neglecting the possible dangers. The content

of majority DPLs studied were found to be misleading rather than educative. There is an urgent need for regulatory authorities to enforce the need to meet WHO 1988 criteria for DPLs by PCs. The DPLs presented to the physicians by PCs companies should not contain false claim, catchy statement, or unnecessary materials. Awareness should be created among doctors to ensure a thorough assessment of DPLs before using them as a guide. The information provided by the DPLs should be genuine and reliable. There is need to conduct more studies in more hospitals to generalize these findings.

Acknowledgments

We are grateful to the Faculty of Medicine and Health Sciences, Universiti Sultan Zainal Abidin for their kind cooperation in every step of our work.

References

1. Mikhael EM. Drug promotion in Iraq and its negative effect on both personal and country budget. Int J Pharm Pharm Sci. 2015a;7(1):1.
2. Chitnis K, Limaye A, Bhosale M. Pharmaceutical promotional literature: opinions of physicians in a tertiary care hospital in Mumbai. Int J Basic Clin Pharmacol. 2013;2(5):541–47.
3. Khakhkhar T, Mehta M, Shah R, Sharma D. Evaluation of drug promotional literatures using WHO guidelines. J Pharm Negative Results. 2013;4(1):33–38.
4. Jadav SS, Dumatar CB, Dikshit RK. Drug promotional literatures (DPLs) evaluation as per World Health Organization (WHO) criteria. J App Pharm Sci. 2014;4(6):84–8.
5. Jaykaran, Saxena D, Yadav P, Kantharia ND. Drug promotional literature distributed by pharmaceutical companies: Do they provide enough information to ascertain their validity? J Pharmacol Pharmacother. 2011a;2(3):192–194.
6. Mall SN, Dudhgaonkar S, Bachewaz NP. Evaluation of rationality of drug promotional literature using World Health Organisation guidelines. Indian J Pharmacol. 2010;42(5):267–272.
7. Garje YA, Ghodke BV, Lalan HN. Assessment of promotional drug literature using World Health Organisation (WHO) Guidelines. Indian J Appl Res. 2014;4(2):3–5.
8. Phoolgen S, Kumar SA, Kumar JR. Evaluation of the rationality of psychotropic drug promotional literatures in Nepal. J Drug Deliv Ther. 2012;2(6):6–8.
9. Jaykaran, Saxen D, Yadav P, Kantharia ND. Metaphors and symbols in drug promotional literatures distributed by pharmaceutical companies. Natl J Physiol Pharm Pharmacol. 2011b;1:32–34.
10. World Health Organization. *Ethical Criteria for Medicinal Drug Promotion*. Resolution WHA41.17 adopted by the Forty-first World Health Assembly, 13 May 1988. Available at: http://apps.who.int/iris/bitstream/10665/38125/1/924154239X_eng.pdf?ua=1.
11. Abubakar AR, Simbak NB, Haque M. Adverse drug reactions: predisposing factors, modern classifications and causality assessment. Research J Pharm Tech. 2014a;7(9):1091–1098.
12. Krishnamurthy B, Murthy MB. Authenticity of claim made in drug promotional literatures. Indian J Pharmacol. 2010;42(1):57–61.
13. Abubakar AR, Chedi BAZ, Simbak NB, Haque M. Medication error: The role of health care professionals, sources of error and prevention strategies. J Chem Pharm Res. 2014b;6(10):646–51.
14. Goodman B. Do drug company promotions influence physician behavior? West J Med. 2001;174(4):232–233.
15. Dana J, Loewenstein G. A social science perspective on gifts to physicians from industry. JAMA. 2003;290(2):252–255.
16. American Medical Students. *An Overview of the Literature:* "Does that One Slice of Pizza Matter ?" Available at: http://www.amsa.org/prof/nofreelunch.pdf.
17. Pharmaceutical Representatives: An Evidence-Based Review with Suggested Guidelines for Clerkships Available at. http://www.ncfh.org/pdfs/PIRT9.pdf Pharmaceutical Representatives: An Evidence-Based Review with Suggested Guidelines for Clerkships. Available at: http://www.ncfh.org/pdfs/PIRT9.pdf.
18. Jureidini J, Mansfield P. Does drug promotion adversely influence doctors' abilities to make the best decisions for patients? Australas Psychiatry. 2001;9(2):95–99.
19. Zaki NM. Pharmacists' and physicians' perception and exposure to drug promotion: A Saudi study. Saudi Pharm J. 2014;22(6):528–36.
20. Sierles FS, Brodkey AC, Cleary LM, McCurdy FA, Mintz M, Julia F, et al. Medical students' exposure to and attitudes about drug company interactions: a national survey. JAMA. 2005;294(9):1034–1042.
21. Spurling GK, Mansfield PR, Montgomery BD, Lexchin J, Doust J, Othman N, Vitry AI. Information from pharmaceutical companies and the quality, quantity, and cost of physicians' prescribing: a systematic review. PLoS Med. 2010;7(10):e1000352.
22. Haque N, Haque M, Sultana R, Kawsar S, Islam MDZ, Chowdhury SN, Anwar AKMN. Teaching medical students the skills required to critically evaluate the drug information sources for rational prescribing – A report of an exercise on evaluation of prescribing information. Bangladesh J Physiol Pharmacol. 2005;21(1):1–4.
23. Salam A, Haque M, Islam MZ, Helali AM, Yousuf R, Yesmin F, Alattraqchi AG, Rao USM. Comparative study of professionalism of future medical professionals among three private medical colleges of Bangladesh. Asian J Pharm Clin Res. 2013;6(3):170–79.
24. Rahman NIA, Aziz AA, Zulkifli Z, Haj MA, Nasir FHM, Pergalathan S, Hamidi MI, Ismail SB, Simbak NB, Haque M. Perceptions of students in different phases of medical education of the educational environment: Universiti Sultan Zainal Abidin. Adv Med Educ Pract. 2015;6:211–22.
25. Islam SB, Salam A, Alattraqchi AG, Annamalai L, Chockalingam A, Dali WPEW, Rahman NIA, Abubakar AR, Haque M. Evaluation of doctors' performance as facilitators in basic medical science lecture classes in a new Malaysia medical school. Adv Med Educ Pract. 2015;6:231–37.
26. Mikhael EM. Evaluating the reliability and accuracy of the promotional brochures for the generic pharmaceutical companies in Iraq using World Health Organization guidelines. J Pharm Bioallied Sci. 2015b;7(1):58–61.

How to cite this article: Abubakar AR, Sheikh SA, Haque M. Drug promotional literatures: Educative or misleading for young medical graduates and students?. Natl J Physiol Pharm Pharmacol 2015;5:318-322.

Source of Support: Nil, **Conflict of Interest:** None declared.