

## Snapshot of the pharmaceutical promotional literature of Bangladesh: A critical review

Fatema Johora and Md. Sayedur Rahman

Department of Pharmacology, Faculty of Basic Science and Paraclinical Science, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh.

### Article Info

Received: 22 May 2018  
Accepted: 27 June 2018  
Available Online: 14 July 2018  
DOI: 10.3329/bjp.v13i3.36752

### Cite this article:

Johora F, Rahman MS. Snapshot of the pharmaceutical promotional literature of Bangladesh: A critical review. Bangladesh J Pharmacol. 2018; 13: 214-21.

### Abstract

The present research was conducted to evaluate the quality of pharmaceutical promotional literature. Indications was mentioned in 88.2% promotional literature and less than half (40.0, 33.9 and 38.9%) of these contains side effects, precautions and contraindications respectively. Among the provided information 67.3%, 16.5%, 19.5% and 24.0% matched with the BDNF/BNF respectively. Scientific articles (73.3%) were cited most followed by commercial online sources (15.5%), data on file (4.2%), regulatory body approval data (2.9%), product monograph (2.7%) and textbook/reference book (1.6%). Only half (50.2%) of these cited references were retrievable and no 'data on file' could be retrieved. Though most (73.2%) of the promotional claims were true, 13.7, 5.9, 4.6 and 2.6% were identified as false, exaggerated, ambiguous and controversial respectively. This revelation about the quality of promotional literature might be an eye opener for the policy makers. More importantly, this may bring alertness among the physicians during interpretation of pharmaceutical promotion literature.

### Introduction

Physicians are expected to have concern about the best interest of the patients (Daher, 2013). In response to that expectation, the physicians appear to have interest to update their knowledge about medicine. Actually, this anticipated interest of physicians provided opportunity to the pharmaceutical companies to offer information through the promotional activities in the name of education (May, 1961). Printed promotional materials are the most commonly used promotion tool (Ijoma et al., 2010; Alssageer and Kowalski, 2012) and are designed to introduce product to prescriber as well as to increase knowledge about that promoted product by reinforcing the verbal message provided by the medical representatives (Alssageer and Kowalski, 2012). Several studies shows that provision of information on medicine usually contaminated with the intentional manipulation and misinterpretation as well as claims, which

are often inaccurate, exaggerated, ambiguous, controversial, oversimplified, irrelevant and false (Norris et al., 2005; Rohra et al., 2006; Othman et al., 2009; Murthy and Krishnamurthy, 2010; Jaykaran et al., 2011; Mikhael, 2015; Randhawa et al., 2015). In addition, essential information like contraindications, warnings and side effects are sometimes absent (Mali et al., 2009; Khakhkhar et al., 2013; Mikhael, 2015).

Bangladesh had formulated a Code of Pharmaceutical Marketing Practices (CPMP) in 1994 to promote and support continuous development of and strict adherence to the ethical principles of marketing of pharmaceutical products (DGDA, 1994; Rahman et al., 1999). Rahman et al. (1999) found that the CPMP failed to ensure minimum scientific information in the drug advertisement. In Bangladesh, gross quantitative and qualitative variations were observed, when information provided in the advertisements was compared with



independent source (Haque et al., 2005). The pharmacology education was inadequate to prepare the future physician to combat this situation (Rahman, 1995; Rahman, 1999; Begum et al., 1999) and consequently, the misleading claims appearing in the printed promotional literature worsened the situation (Islam and Farah, 2007). Present study was conducted in this backdrop, adherence of promotional literature to existing Code of Pharmaceutical Marketing Practice was evaluated along with scientific authenticity of the promotional claims of some selected medicinal products.

## Materials and Methods

Pharmaceutical promotional materials were collected from selected inpatient and out patient departments of BSMMU. Large designed and labelled envelopes were provided to the clinical staffs (medical officers, residents and postgraduate students) to store the promotional materials which they receive from representatives of pharmaceutical companies during one week of study period (study weeks were chosen with 6 working days in each). One similar envelope was also kept with one faculty member of the respective departments for the same purpose and period. Next week, all promotional materials stored in the envelope were collected by the researcher.

Pharmaceutical promotional literature were screened and separated from other promotional materials. Then only promotional literature were evaluated for the rest of the study.

Step I: Total number of promotional literature of each department was counted. Step II: Promotional literature were categorized into allopathic, Unani, Ayurvedic, herbal, cosmetics, medical device and other. Step III: Promotional literature other than allopathic drugs were excluded. Step IV: Allopathic products were categorized and promotional literature other than 'full advertisement' were excluded. Step V: Promotional literature of 'full advertisement' of few products were excluded from the review process due to absence of information about those products in the latest edition of BDNF or BNF. Step VI: Quality of those selected 'full advertisements' was then assessed in two phases.

### Evaluation of adherence

Adherence of all collected promotional literature to the Code of Pharmaceutical Marketing Practices (CPMP) was assessed by a checklist. Among the mentioned parameters of CPMP, presence of selected parameters such as indications, side effects, precautions, contraindications and cited references were assessed. Total 440 promotional literature were evaluated in this phase.

### Evaluation of authenticity

#### Authenticity of the claims (if present)

Later on, promotional claims were evaluated for authenticity. 10 new products (medicinal products those were only present in 4<sup>th</sup> edition of Bangladesh National Formulary but absent in 3<sup>rd</sup> edition of Bangladesh National Formulary) were selected from each department for evaluation of promotional claims. When the number of new products was more than 10, then the products were randomly included to be studied. If promotional literature of the same new medicine was found in other department, only one was included to avoid repetition in order to increase product variability. Medicinal products having multiple promotional literature circulated by different manufacturers were included for separate evaluation. Total 73 promotional literature were evaluated in this phase.

Promotional claims were compared with cited references of promotional literature, original innovator's product monograph and also with independent sources of drug information such as BDNF, reference book, "Martindale: The Complete Drug Reference" and/or websites of different regulatory bodies. In case of any inaccessibility of full paper, their abstracts were retrieved.

If a product was absent in 4<sup>th</sup> edition of BDNF, then latest available edition (67<sup>th</sup>) of BNF was used as an alternative of similar nature. Latest available online edition (36<sup>th</sup>) of "Martindale: The complete drug reference" was used as a reference book because of its updated regulatory viewpoint, which was suitable for this study. Among the websites of regulatory bodies', website of Therapeutic Goods Administration (TGA) of Australia was selected for this study. If, any product was not approved in Australia but approved in Bangladesh, in those cases, websites of Medicine and Healthcare products Regulatory Agency (MHRA) of United Kingdom, Food and Drug Administration (FDA) of United States of America and European Medicines Agency (EMA) of European Union were used for evaluation process. Promotional claims were categorized into true, exaggerated, ambiguous, controversial and false on the basis of research findings, regulatory status and availability of products.

## Results

### Adherence to code of pharmaceutical marketing practice

Table I showed that the printed promotional literature were 77.6, 12.7, 5.0, 2.7, 0.5, 0.12 and 1.2% for allopathic, cosmetic, herbal, Unani, Ayurvedic, device and others respectively.

Table I	
Types of products promoted by the promotional literature	
Types of products	Proportion of promotional literatures (n = 810)
Allopathic product	77.6%
Cosmetic products	12.7%
Herbal product	5.0%
Unani products	2.7%
Ayurvedic products	0.5%
Device (medical)	0.1%
Others	1.2%

All reviewed promotional literature (100.0%) contained name of the active ingredient, trade name and detail information about license holder. Active ingredient per dosage formulation, approved dosage schedule, route of administration was mentioned in 88.9, 66.4 and 86.6% of the reviewed promotional literature respectively (Table II).

Indications, side effects, precautions and

Table II	
Availability of information in the promotional literature according to Code of Pharmaceutical Marketing Practices (CPMP)	
	Proportion of promotional literatures that contains the information (n = 440)
Name of active ingredient	100.0%
Trade name	100.0%
Active ingredient per dosage formulation	88.9%
Approved dosage schedule	66.4%
Route of administration	86.6%
Indications	88.2%
Side effects	40.0%
Precautions	33.9%
Contraindications	38.9%
Detail information about license holder	100.0%

Table III	
Provided information matched with BDNF/BNF	
	Proportion of information matched with BDNF/BNF*
Indications	67.3% (261/388)
Side effects	16.5% (29/176)
Precautions	19.5% (29/149)
Contraindications	24.0% (41/171)

contraindications were mentioned in 88.2, 40.0, 33.9 and 38.9% respectively. Regarding indications, 67.3% (261/388) promotional literature matched with BDNF/BNF. While regarding side effects, precautions and contraindications 16.5% (29/176), 19.5% (29/149) and 24.0% (41/171) promotional literature matched with BDNF/BNF (Table III).

Table IV showed that 1,020 references were mentioned in 440 promotional literature, of which scientific article,

Table IV	
Types of documents cited as reference in promotional literature	
Types of documents	Proportion of references (n = 1020)
Scientific article	73.3%
Commercial online information sources	15.5%
Data on file	4.2%
Regulatory body approval data	2.9%
Product monograph	2.7%
Textbook/Reference book	1.6%

commercial online information sources, data on file, regulatory body approval data, product monograph and textbook/reference book were cited as reference in 747 (73.3%), 158 (15.5%), 43 (4.2%), 29 (2.9%), 27 (2.7%)

Table V	
Retrievability of the references cited in promotional literature	
Types of documents	Proportion of references retrievable
Scientific article	60.8% (454/747)
Commercial online information sources	18.4% (29/158)
Product monograph	81.5% (22/27)
Regulatory body approval data	3.5% (1/29)
Textbook/Reference book	37.5% (6/16)
Data on file	0.0% (0/43)
Total	50.2% (512/1020)

and 16 (1.6%).

Out of 1020 references mentioned in the literature, retrieval was possible in 512 (50.2%) cases. Among these retrieved documents, 454, 29, 22, 6 and 1 references were from scientific article, online commercial sources, product monograph and textbook/reference book and regulatory body approval data respectively. None of the reference from data on file was retrievable (Table V).

Total 153 promotional claims were present in 73 promotional literature of which 98 (64.1%), 46 (30.1%), 4 (2.6%), 1/153 (0.7%), 3 (2.5%) and 1 (0.7%) were about

Table VI	
Categorization of promotional claims	
Area of claims	Proportion of claims (n = 153)
Efficacy	64.1%
Safety	30.1%
Cost	2.6%
Pharmaceuticals	0.7%
Pharmacokinetics	2.5%
Others	0.7%

Table VII	
Authenticity of the promotional claims	
	Proportion of claims (n = 153)
True	73.2%
Ambiguous	4.6%
Exaggerated	5.9%
Controversial	2.6%
False	13.7%

efficacy, safety, cost, pharmaceutical property, pharmacokinetic property and others respectively (Table VI). Out of 153 claims, 112 (73.2%), 7 (4.6%), 9 (5.9%), 4 (2.6%) and 21 (13.7%) were found to be true, ambiguous, exaggerated, controversial and false respectively (Table VII).

## Discussion

Promotional literature are considered as the most widely used pharmaceutical promotional tools, though claimed to be educational materials, the authenticity of provided information is questionable (Avorn et al., 1982). Interactions of physician-pharmaceutical industry have been commenced with the motto of 'keeping modern in medicine' (Greene and Podolsky, 2009).

In the present study, name of the active ingredient with trade name along with detail information about license holder was mentioned in all promotional literature like previous studies (Jadav et al., 2014; Michael, 2015). However, essential prescribing information like therapeutic indication, side effects, precautions and contraindications were present in promotional literature in varying degree (88.2, 40.0, 33.9 and 38.9%), which corresponds with some of the previous researches (Alam et al., 2009; Khakhkhar et al., 2013). High proportion of exaggerations in case of indications and/or omissions of safety information correspond with a study conducted in Bangladesh (Haque et al., 2005). Scientific articles were cited as references in large proportion

(73.3%) of materials, but half of them could not be retrieved, which matches with earlier studies conducted in India (Mali et al., 2010; Randhawa et al., 2015). Similar to Mali et al. (2010), proportion (24.8%) of promotional materials found to cite references from commercial online information sources. Like previous similar studies (Mali et al., 2010; Saibhavana et al., 2015), most (64.1%) of the promotional claims were focused on efficacy of the product rather than safety or cost. Presence of true claim (73.2%) was less than that of another similar study (Rohra et al., 2006). Prevalence of exaggerations (5.9%) corresponds with a study conducted in a developing country (Randhawa et al., 2015). Similar to some previous studies (Rohra et al., 2006; Murthy and Krishnamurthy, 2010), a small proportion of promotional claims were either ambiguous (4.6%) or controversial (2.6%) or false (13.7%). The quality of promotional literature indicates the necessity of caution on the part of physicians while interpreting the claims mentioned in these. The policy makers and educators may find these findings interesting to take required regulatory measure.

## Conclusion

The printed promotional materials contain exaggerated claims and other deviations from the standard.

## References

- Alam K, Shah AK, Ojha P, Palaian S, Shankar PR. Evaluation of drug promotional materials in a hospital setting in Nepal. *Southern Med Rev.* 2009; 2: 2-6.
- Allsageer MA, Kowalski SR. A survey of pharmaceutical company representative interactions with doctors in Libya. *Libyan J Med.* 2012; 2012.
- Allsageer MA, Kowalski SR. Doctors' opinions of information provided by Libyan pharmaceutical company representatives. *Libyan J Med.* 2012; 2012.
- Avorn J, Chen M, Hartley R. Scientific versus commercial sources of influence on the prescribing behavior of physicians. *Am J Med.* 1982; 73: 4-8.
- Begum M, Rahman MS, Islam AFMS, Khan IA, Akhter N. Eleven years of the undergraduate medical curriculum 1988: Review on the changes in pharmacology written questions. *Bangladesh J Physiol Pharmacol.* 1999; 15: 27-30.
- Daher M. Ethical issues in the geriatric patient with advanced cancer 'living to the end'. *Ann Oncol.* 2013; 24: 55-58.
- Directorate General of Drug Administration (DGDA). Code of pharmaceutical marketing practices. Directorate general of drug administration. Dhaka, 1994.
- Greene JA, Podolsky SH. Keeping modern in medicine: Pharmaceutical promotion and physician education in postwar America. *Bull Hist Med.* 009; 83: 331-77.

- Haque N, Haque M, Sultana R, Kawsar S, Islam MZ. Teaching medical students the skills required to critically evaluate the drug information sources for rational prescribing-report of an exercise on evaluation of prescribing information. *Bangladesh J Physiol Pharmacol*. 2005; 21: 1-4.
- Ijoma U, Onwuekwe I, Onodugo O, Agawa E, Ejim E, Onydum C, Onah E, Okwudire E, Ogwuonah G. Effect of promotional strategies of pharmaceutical companies on doctor's prescription pattern in South-East Nigeria. *TAF Prev Med Bull*. 2010; 9: 1-6.
- Islam MS, Farah SS. Misleading promotion of drugs in Bangladesh: Evidence from drug promotional brochures distributed to general practitioners by the pharmaceutical companies. *J Pub Health*. 2007; 29: 212-13.
- Jadav SS, Dumatar CB, Dikshit RK. Drug promotional literatures (DPLs) evaluation as per World Health Organization (WHO) criteria. *J Appl Pharmaceut Sci*. 2014; 4: 84-88.
- Jaykaran DS, 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*. 2011; 2: 192-94.
- Khakhkhar T, Mehta M, Shah R, Sharma D. Evaluation of drug promotional literatures using WHO guidelines. *J Pharma Neg Res*. 2013; 4: 33-38.
- Mali SN, Dudhgaonkar S, Bachewar NP. Evaluation of rationality of promotional drug literature using World Health Organization guidelines. *Ind J Pharmacol*. 2010; 42: 267-72.
- May CD. Selling drugs by 'educating' physicians. *J Med Educat*. 1961; 36: 1-23.
- Mikhael EM. Evaluating the reliability and accuracy of the promotional brochures from the generic pharmaceutical companies in Iraq using World Health Organization guidelines. *J Pharma Bioallied Sci*. 2015; 7: 65-68.
- Murthy MB, Krishnamurthy B. Authenticity of claims made in drug promotional literature. *Ind J Pharmacol*. 2010; 42: 59-60.
- Norris P, Herxheimer A, Lexchin J. Drug promotion: What we know, what we have yet to learn. World Health Organization/Health Action International, Geneva, Switzerland, 2005.
- Othman N, Vitry A, Roughhead EE. Quality of Pharmaceutical Advertisements in Medical Journals: A Systemic review. *PLoS One*. 2009; 4: 7, e 6350.
- Rahman MS, Begum M, Haque MZ, Akhter N. Drug advertisement in medical journals. *Bangladesh J Physiol Pharmacol*. 1999; 15: 31-36.
- Rahman MS. Changes required in pharmacotherapy teaching to ensure rational use of drugs (letter to the editor). *Bangladesh J Physiol Pharmacol*. 1995; 11: 38-39.
- Rahman MS. New global situation in drug regulation: Redefine responsibility of the pharmacologists of Bangladesh. *Bangladesh J Physiol Pharmacol*. 1999; 15: 41-42.
- Randhawa GK, Singh NR, Rai J, Kaur G, Kashyap R. A critical analysis of claims and their authenticity in Indian drug promotional advertisements. *Advan Med*. 2015; 2015.
- Rohra DK, Gilani AH, Memon TK, Perven G, Khan MT, Zafar H. Critical evaluation of claims made by pharmaceutical companies in drug promotional material in Pakistan. *J Pharmacol Pharmaceut Sci*. 2006; 9: 50-59.
- Saibhavana D, Mukta CN, Nithyananda CK. Critical evaluation of drug promotional literature for drug used in cardiovascular diseases. *Int J Pharma Pharmaceut Sci*. 2015; 7: 405-07.

**Author Info**

Md. Sayedur Rahman (Principal contact)

e-mail: srkhasru@bsmmu.edu.bd

Supplementary Table I			
Claim of efficacy			
Name of the medicine	Claim	Anti-claim statement	Remarks
Aprepitant	Superior to ondansetron for the prevention of vomiting	Not supported by reference	False claim
Aprepitant	Indicated for prevention of general nausea and vomiting		Ambiguous claim
Bisoprolol	Most selective Beta-blocker	Has higher degree of Beta selective activity than Atenolol, metoprolol but less than Nebivolol	Exaggerated
Bisoprolol	Provides a superb option for the management of hypertension		Ambiguous
Carbetocin	Superior to oxytocin	Decrease reduction in the use of additional uterotonics but no difference in blood loss	Exaggerated claim
Ceftibuten	Effective where other fails	Similar to cefixime	False claim
Ceftibuten	Better clinical efficacy in complicated urinary tract infection (with illustration)	Success rate was 78.3% in ceftibuten group and 77.3% in cefixime group, as effective as cefixime	Exaggerated claim
Ceftibuten	Better than cefprozil (with illustration)	Success rate was 83.3% in Ceftibuten group and 82.5% in Cefprozil group	
Dapoxetine	Provides similar or more efficacy with on-demand therapy compared to once-daily Paroxetine	An on-demand dose of 30 mg dapoxetine is no more effective than the currently prescribed paroxetine	False claim
Doxophylline	Superior to theophylline in terms of efficacy	Not supported by reference	
Doxophylline	The ultimate choice for asthma and COPD		Ambiguous claim
Duloxetine	Established analgesic efficacy across 4 different chronic pain conditions	TGA rejected the indication in chronic low back pain and osteoarthritis	Exaggerated claim
Linalgiptin	Improves long-term diabetic management	Not supported by reference	False claim
Olmesartan plus amlodipine	Powerful double digit blood pressure reduction (↓ SBP up to 20.6 mmHg)	↓ SBP up to 16.5 mmHg	Exaggerated
Olmesartan plus hydrochlorothiazide	For high systolic blood pressure	For mild to moderate hypertension	Exaggerated claim
Pregabalin	Quick solution of chronic pain		Ambiguous claim
Pregabalin	Quick solution of chronic pain		
Solifenacin	Significantly improves urgency episodes compared to tolterodine immediate release	As effective as tolterodine	Controversial

Supplementary Table II

Claim of safety			
Name of the medicine	Claim	Anti-claim statement	Remarks
Aprepitant	Safer than ondansetron	Not supported by evidence	False claim
Aprepitant	Indicated in morning sickness during pregnancy	Contraindicated in pregnancy, no such indication was found	
Azilsartan	Safe for hepatic and renal impairment patients	Consider lower starting dose, avoid in severe hepatic impairment; Caution should be advised in severe renal impairment	
Carbetocin	Safer than oxytocin	Safety profile is similar to oxytocin	
Ceftibuten	Safe than conventional	Not supported by reference	
Ceftibuten	More tolerable to liver	Slight elevation of serum level of liver transaminase was 6.5% in both group (Ceftibuten and Cefixime)	
Deflazacort	1st choice corticosteroid for diabetic patients	Not supported by evidence	False
Deflazacort	Less side effects than methylprednisolone	Some reference suggests, some don't	Controversial
Deflazacort	Less likely to cause hypertension	Not supported by evidence, controversial statement was found	Controversial claim
Difluprednate	No chance of IOP rise in long term use	Possible elevation in IOP may be substantially higher than commonly encountered with other topical steroids	False claim
Drospirenone plus ethinylestradiol	No effect on blood pressure	Increased blood pressure as adverse effect	
Drospirenone plus ethinylestradiol	Least chance of weight gain	Chance of weight gain	Exaggerated claim
Glucosamine sulfate plus diacerein	Safe for patients with renal impairment	Doses of Glucosamine should be adjusted in patients with renal impairment	False claim
Linagliptin	Safe for hepatic impaired patient without dose adjustment	Should not be used in patient with severe hepatic impairment	False
Linalgiptin	Suitable for diabetic patient with cardiac problem	Safety data is not adequate, may be a new option but invite continue analysis	Exaggerated claim
Loteprednole	Excellent safety profile in terms of IOP elevation than other corticosteroids	Not supported by evidence	False claim
Mirabegron	Less side effects than others	Less antimuscarinic side effects than others	Exaggerated claim
Nepafenac	Has the least chance of ocular surface complications	Not supported by evidence	False claim
Olmesartan plus amlodipine	Standard fixed dose combination reduces adverse events compared to high dose monotherapy	The profile of drug related adverse events was similar	
Sodium alginate plus potassium bicarbonate	Safest antiulcerant for pregnant women	No comparative study was found	
Trimetazidine	Effectively decrease the incidence of CIN	Trimetazidine intake before elective PCI in diabetic patients with mild-moderate renal dysfunction is associated with decrease incidence of CIN	Exaggerated

<b>Supplementary Table III</b>			
<b>Claims about pharmacokinetics and general benefit</b>			
<b>Name of the medicine</b>	<b>Claim</b>	<b>Anti-claim statement</b>	<b>Remarks</b>
Dapoxetine	Rapid absorption rate		Ambiguous claim
Ebastine	Rapid onset of action		
Linagliptin	Patient will get treatment confidence		Ambiguous