

**Original article**

**Drug promotional brochure as a source of drug information in Bangladesh: a critical analysis of the brochures for the authenticity of information.**

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**Abstract**

**Background**

Pharmaceutical companies are the only information providers to the health professionals in Bangladesh. It is well-known that misleading drug promotion is quite common in Bangladesh. But no study is conducted till now to gauge the nature and prevalence of misleading promotion in the country.

**Methods**

A convenience sample of 115 drug promotional brochures was collected from top 10 practicing general practitioner of a district town of Bangladesh. Promotional claims from those brochures were critically analyzed and compiled with the help of currently available medical literatures. Promotional claims not substantiated by proper scientific evidences were considered as misleading claims. The misleading claims were further categorized debatable, overstated, and ambiguous and forged to specify the nature of misleading claims for better understanding.

**Results**

About 34% of the total promotional claims were found to be misleading from the evaluated promotional brochures. Of the total

misleading claims, 50% were based on unsettled evidences and about 22% were presented exaggeratedly in those promotional brochures. Prevalence of ambiguous and forged claims was reported to be about 16% and 12% respectively.

**Conclusions**

Prevalence of misleading claims in the pharmaceutical promotional brochures appeared to be high in Bangladesh. Such misleading promotion may lead to inappropriate prescribing of drugs by the health professionals.

**Keywords:** drug promotional brochure; misleading claims; third world countries;

**Introduction**

The term 'promotion' refers to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.<sup>1</sup> Promotion of drugs include activities of medical representatives, distribution of drug information brochures, provision of gifts and samples, direct-to-consumer advertisements, holding of conferences, symposium and scientific meetings, sponsoring of medical education and conduct of promotional trials.

The pharmaceutical industries throughout the world are heavily involved in aggressive drug promotions.<sup>2,3</sup> Evidences suggest that extensive pharmaceutical promotion can create a potential for ethical dilemma because such activities may influence physician prescribing behavior without necessarily benefiting the patient.<sup>3-8</sup>

As promotional can change prescribing behaviors of the health professionals, the messages of promotion should be factual, evidence-based, unambiguous and balanced.<sup>2,7</sup> Unfortunately, promotion is neither factual nor evidence-based in many countries of the world. Admittedly, abundance of inaccurate and inappropriate promotional claims may contribute to irrational drug use.<sup>2,9</sup> Health professionals are still provided with grossly exaggerated claims all over the world.<sup>10</sup> As a major promotional technique of direct-to-physician, pharmaceutical companies frequently employs promotional brochures, based on different types of clinical studies.<sup>3</sup> But these promotional brochures make immoral use of scientific studies. Information in these materials is often taken from disputable clinical studies.<sup>7</sup>

As with many countries, drug promotional activities constitute a major part of the entire operations of pharmaceutical manufactures in Bangladesh. Direct-to-customer promotion is a very common practice here using different types of printed materials displaying the good and bad aspects of the concerned drugs. It is generally believed that over-statements and misinformation is a part of the promotional activities of drug companies in Bangladesh. Moreover, drug companies are the only organizations to provide information to health care providers in the country.<sup>11</sup> Thus, there is every potential for misleading promotion of drugs in Bangladesh.

No study has been conducted yet to measure the nature and extent of promotional activities

of pharmaceutical companies in Bangladesh. This analytical study was undertaken to explore the characteristics of information provided in the promotional brochures. Particular objective of this study was to gauge the prevalence of misleading promotional claims in the promotional brochures disseminated among general practitioners of Bangladesh.

## Materials and Methods

### Sample Selection

This exploratory study was based on critical evaluation of drug promotional brochures. Promotional brochures containing claims for the drugs, which were circulated by the pharmaceutical representatives, were collected from the offices of top 10 practicing General practitioner of a district town (Chuadanga) of Bangladesh. In Bangladesh, top General practitioners are the most important targets of the pharmaceutical companies for promoting their drugs. Randomization of the subjects was not possible because there was no specific database for the practicing general practitioner at present. For this, the sample subjects were selected using convenience sampling method. The general practitioners were ranked on the basis of highest number of patients they see per day.

### Data collection

The brochures were collected from the selected general practitioner offices during the month of November (05-30), 2006. Similar brochures of the same products or brochures containing short messages were excluded from the study. In addition, brochures presented more than one product was also excluded. Finally, 115 promotional brochures were evaluated for necessary information.

### Data Analysis

Promotional claims not substantiated by proper scientific evidences were considered as misleading claims. The misleading claims

were further categorized as below to specify the actual nature of misleading claims:

**Debatable claim:** when the claim was found to be open to question that is controversial in nature or not settled scientifically.

**Overstated claim:** when an insignificant merit of a drug was found to be magnified intentionally and unnecessarily to make it a significant one.

**Ambiguous claim:** when a claim was found to be inexplicable or unclear in the promotional brochures.

**Forged claims:** when the claim in the question was found to be beyond the truth.

The promotional claims printed on the brochures were critically analyzed and compiled by two graduate pharmacists taking help from currently available evidences in the medical literatures. The medical literatures comprised mostly of published research articles and were retrievable from the Internet. Literature search was performed for every claim using relevant key words.

## Results

One hundred and fifteen promotional brochures covering 60 different drug molecules from different pharmaceutical companies were taken for critical evaluation. A total of 341 claims were recorded from these brochures. Of these, 116 (34.02%) claims were found to be misleading in nature. Half (50%) of the total misleading claims were reported to be controversial while about 22% claims were presented exaggeratedly. The rest of the misleading claims were either ambiguous or false. **Table 1** below provides a brief illustration of the characteristics of promotional claims.

**Debatable claims:** Of the total misleading claims, most were reported to be controversial, which are still under rigorous scientific investigations and have not been

substantiated completely. For instance, promotional brochures on omeprazole variously claimed it to be 'superior to other available proton pump inhibitors (PPIs)'. But evidence showed no significant difference between equivalent doses of PPIs.<sup>12</sup> In some cases, atorvastatin was found to be presented as 'a superior lipid lowering agent' compared to other statins. But superiority of atorvastatin over other statins in lowering lipid is still not well-established as found in one recent study.<sup>13</sup> A brief list of some debatable claims has been included in the following **Table 2**. (see below the references)

**Overstated claims:** Around 22% claims were found to be placed exaggeratedly in the promotional brochures. For example, one claim made for calcium supplement stated that it 'builds robust body structure and increases productivity at work and play' for children. But evidence from a meta-analysis showed that calcium has little effect on bone development in healthy children.<sup>28</sup> In fact, there is no convincing mechanism by which calcium can help in developing stout body structure in children. Another such inflated claim was found for clopidogrel plus aspirin, which mentioned the combination as 'the best coalition against blood clotting'. But, evidence showed that such combination has small benefit, which is overshadowed by significant life-threatening bleeding.<sup>29</sup> In another example, gatifloxacin was presented with excellent safety profile. But it was found to be associated with life-threatening hyperglycemia and hypoglycemia.<sup>30</sup> Some important overstated claims have been summarized in the following **Table 3**.

**Ambiguous claims:** There were many (about 16%) ambiguous promotional statements about various drugs were encountered during the present study. One such example can be mentioned for calcitriol, which stated 'it can add smile to your life'. It is difficult to make sense to whom it will 'add smile', the doctor or the patient! Admittedly, calcitriol has nothing to

do with adding smile to someone's life. Further, another interesting claim for clonazepam was presented as it 'ensures freedom to fly'. Clonazepam is not a euphoric drug in anyway to ensure 'freedom to fly'? Some examples of ambiguous claims have been given in the following **Table 4**.

**Forged Claims:** Some promotional claims (12%) were found to be completely beyond the truth in this study. One such example can be cited for midazolam tablet where it was shown 'superior to parenteral preparations' of midazolam. But the truth is 'onset and duration of action is greater with parenteral midazolam'.<sup>37</sup> Another false statement was found for valdecoxib where the promotional claim was presented as 'safer in terms of cardiovascular risks'. Conversely, valdecoxib was withdrawn from the world market due to its cardiovascular toxicity.<sup>24</sup> A brief list of forged claims has been depicted in the **Table 5**.

## Discussions

### Main findings of the study

Prevalence of misleading claims in the promotional brochures appeared to be high (34.02%) in Bangladesh. Of the total misleading claims, 50% were based on debatable evidences, supported by concrete scientific supports. Overstated claims accounted for around 22% of the entire unjustifiable promotional claims. In addition, rates of ambiguous and false claims were reported as 16.38% and 12.07% respectively.

### What is already known on this topic?

Comparatively lower rates (18%) of misleading claims were found in the promotional booklets circulated to the general practitioner in Pakistan.<sup>8</sup> However, variable rates of misleading claims in the printed materials targeting the physicians were found in other studies. In a Spanish study, 44.1% unsubstantiated claims were reported in medical journals advertisements.<sup>42</sup> In another

study of the advertising material and marketing brochures sent out by drug companies to General practitioner in Germany showed about 94% of the information in these brochures with no basis in scientific evidence.<sup>43</sup> Again, a US based cross-sectional study reported only 39% of the promotional items, excluding gifts and drug samples, offered scientific support for their claims.<sup>44</sup>

Pharmaceutical companies are still considered as the most important sources of information among General practitioner despite the apprehensions about the truthfulness of the promotional claims.<sup>8</sup> For this, the accuracy and validity of the information presented in promotional brochures is important because many physicians rely heavily on such information while making prescribing decision.<sup>3</sup> Although much of the promotional information health professionals receive from the pharmaceutical industry is based on good evidence, this is not always the case.<sup>45</sup> Previous study showed that 21% of the promotional claims were controversial of the total misleading claims reported.<sup>8</sup>

Information in the promotional materials is often presented with magnified benefits having little importance in practice. In an analytical study, researchers identified about 32% overstated claims of the total unjustifiable claims.<sup>8</sup> Another study in the US found 15% exaggerated claims in the brochures distributed to the family doctors by drug companies.<sup>46</sup> Pharmaceutical companies often use promotional materials that make unsubstantiated claims of superiority over competing products in order to win the competitive market.<sup>6</sup> Bangladesh is one of the largest pharmaceutical markets of the world for generic drugs and drug companies are the only organizations in Bangladesh to provide information to health care providers.<sup>11</sup> Obviously, the market is very competitive and drug companies are mostly dependable on exaggerated claims in their promotional

materials to prove superiority of their products. It is evident that information provided by pharmaceutical companies is not always of good standards.<sup>45</sup> They often promote drugs based on false information. Earlier study in Pakistan showed 26% false claims of the total unjustifiable claims in pharmaceutical promotional brochures.<sup>8</sup>

Unethical promotional approaches including expanded indications and exaggerated efficacy are usual practices of pharmaceutical industries in the south Asian countries.<sup>8,11,47</sup> Logically, the pharmaceutical industry has the right to promote its products but it should do so in a fair, accurate, and ethical manner.<sup>2</sup> Studies have shown that promotional claims made by pharmaceutical companies are often misleading.<sup>5</sup> At present, misleading promotion has become a community concern as this can undermine the public's trust in health professionals and it may encourage inappropriate prescribing. Ironically, misleading promotion has appeared to be a vicious circle between the drug companies and health professionals that does more harm than good.<sup>48,49</sup>

#### **What this study adds?**

This study provides an idea about the prevalence of misleading drug promotion in

Bangladesh. A detailed characteristic of misleading drug promotion has also been explored through this study. This study may act as a guideline for any further comprehensive studies in similar topics.

#### **Limitations of this study**

The present study is associated with certain methodological limitations. Being cross-sectional in nature, the study design fails to measure any concrete outcomes or any cause and effect. The study samples do not represent the entire population because the sample was selected through non-randomized sampling technique. There is a potential for selection bias in the samples due to non-probabilistic sample selection process.

#### **Conclusion**

The present study showed a high level of misleading claims in the pharmaceutical promotional brochures distributed by the drug companies in Bangladesh. These sorts of misleading claims may have possible negative effects on appropriate prescribing in the country. Further, large scale studies are required to gauge actual prevalence of misleading drug promotion and its broad impact on public health.

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**TABLES****Table 1: Characteristics of promotional claims**

Total brochures evaluated:	115
Total drugs identified:	60
Total promotional claims:	341

Types of misleading claims	Number	Prevalence (%)
<b>Total misleading claims</b>	<b>116</b>	<b>34.02</b>
Debatable claims	58	50.00
Overstated claims	25	21.55
Ambiguous claims	19	16.38
Forged claims	14	12.07

**Table 2: Examples of debatable promotional claims**

Drug	Promotional claims	Scientific Evidences
Clopidogrel <i>plus</i> Aspirin	Substantially reduces risks of ischemic events	Combined efficacy does not differ from aspirin alone for reducing ischemic events. <sup>14</sup>
Aspirin	Enteric coating offers maximum protection for stomach	No difference between enteric-coated and uncoated aspirin in reducing GI bleeding or perforation. <sup>15</sup>
Mecobalamin	Significantly reduces depression	Studies failed to show any benefit in depression or mood disorders. <sup>16,17</sup>
Ketorolac	Better efficacy than pethidine and morphine	Comparable efficacy with pethidine at equivalent doses and less effective than morphine. <sup>18,19</sup>
Dexibuprofen	Better analgesic activity than ibuprofen	Equivalent efficacy to ibuprofen in mild to severe somatic and visceral pain. <sup>20</sup>
Domperidone	Excellent efficacy in treating reflux esophagitis	Lack of efficacy in patients with erosive reflux esophagitis. <sup>21,22</sup>
Glucosamine <i>plus</i> Chondroitin	Helps to cure osteoarthritis completely	Shows similar efficacy to placebo in osteoarthritis. <sup>23</sup>
Etoricoxib	Safer than diclofenac in gastrointestinal ulcers	Similar gastrointestinal complications like those of diclofenac. <sup>24</sup>
Sparfloxacin	More efficacious than ciprofloxacin	Ciprofloxacin is significantly more effective than sparfloxacin. <sup>25</sup>
Naproxen	Lower cardiovascular risks in arthritic patients	50% increased cardiovascular risk compared to placebo. <sup>26,27</sup>

**Table 3: Examples of exaggerated promotional claims**

Drug	Promotional claims	Scientific Evidences
Calcitriol	Calcium monotherapy for osteoporosis is only wastage of money	Calcium monotherapy has modest effect in osteoporosis and calcitriol is no better than calcium. <sup>31</sup>
Cefixime	No chance of resistance	Although small, yet cefixime is resistant to many common pathogens. <sup>32</sup>
Ciprofloxacin	100% success rate with 0% resistance	Ciprofloxacin resistance exists in Bangladesh and the trend is increasing. <sup>33</sup>
Aceclofenac	More effective than other NSAIDs in osteoarthritis and rheumatoid arthritis	Shows comparable efficacy with other NSAIDs. <sup>34</sup>
Ursodeoxycholic acid	No adverse effects detected	Although few, but not entirely devoid of side effects. <sup>35</sup>
Calcium (supplement)	Builds <i>robust</i> body structure in children	Has little effect on bone development in healthy children. <sup>28</sup>
Midazolam 7.5mg tablet	Widely used as sedative	Widely used for preoperative sedation but not as general sedatives. <sup>36</sup>

**Table 4: Examples of ambiguous promotional claims**

Drugs	Promotional Claims	Reasons for ambiguity
Zinc (supplement)	Offers a new lease of life	How?
Gliclazide	First line drug for type-2 diabetes	Which type of diabetic patients, obese or lean?
Calcitriol	One in every four women over 50 years has osteoporosis	In which population group or country?
Clonazepam	Ensures freedom to fly	How? Is it a euphoric drug?
Cefradine	The most trusted cephalosporin	Are other cephalosporins unreliable!
Naproxen	Patients with dental pain will be able to take food and will smile after just 8 hours	Eight hours with dental pain!! Why not to take a faster acting NSAID?
Paracetamol	Brings harmony in children's life	How does paracetamol harmonize children's life?

**Table 5: Examples of forged promotional claims**

Drugs	Promotional Claims	Scientific Evidences
Indomethacin	Not recommended in acute gout	The first choice drug of many physicians in gout. <sup>38</sup>
Calcium (as antacid)	One in every 10 persons of Bangladesh suffers from hyperacid secretion, heartburn, dyspepsia, gastritis and peptic ulcer	No related data available. Wrong reference is cited.
Naproxen	Has never yielded any severe cardiovascular risks	Fifty percent (50%) increased cardiovascular risk with naproxen reported compared to placebo. <sup>26</sup>
Diclofenac <i>plus</i> Misoprostol	Misoprostol is safer than lansoprazole as anti-ulcerant	Misoprostol is less tolerable than lansoprazole. <sup>39</sup>
Aripiprazole	Ensures normal mood and behaviour within 10 days	Minimum four to six weeks treatment is required. <sup>40</sup>
Glucosamine <i>plus</i> Chondroitin	Slows down cartilage degeneration	No proof of slowing down cartilage degenerative process or restoration. <sup>41</sup>

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