# Pharmaceutical Promotion in Bangladesh: Assessing the Strength of Regulatory Documents

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**Abstract:** Pharmaceutical promotion is a negative influencing force for prescribing. However, very few regulatory initiatives are taken to overcome this unwarranted influence. The present research was conducted in such context with an attempt to review the regulatory documents related to pharmaceutical promotion in Bangladesh including Code of Pharmaceutical Marketing Practices (CPMP), and to compare CPMP with different global guidelines. The studied guidelines demonstrate effort to regulate promotion, though that varies to a great extent, particularly in enforcement aspects. Clearly defined ethical and legal prohibitions, provisions of punishment for violations and entrusted agency with defined authority are crucial.

**Key Words:** Ethical pharmaceutical promotion, Code of Pharmaceutical Marketing Practices, Drug Policy, Laws, Regulation of promotion, Bangladesh situation

**Background**: Pharmaceutical promotional activities- issue of concern from the very beginning and are highly successful to alter physicians' prescribing habit [1]. The impact of promotion on physicians prescribing practice is enormous, ranging from the selection of inappropriate, unnecessary, costly medicine to low prescribing quality [2-3]. Frequent interactions with industries and positive attitudes towards them have been related with less evidence-based prescribing of physicians [4]. And Weak control over promotional activities has been linked to poor prescribing [5]. There are lots of controversies and no resolution or consensus yet achieved towards this direction. Various interventions have been taken throughout the world to control and regulate pharmaceutical promotional activities [2], [5]. International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and World Health Organization (WHO) acted as pioneers to introduce and develop guidelines to support and encourage the improvement of healthcare through rational use of medicinal drug. In many countries, national guidelines exist, which usually specify that the promotional information should be accurate, complete and good in taste. Guidelines also cover the use of samples, gifts and participation in promotional

conferences as well as in clinical trials [6-8]. However, mere presence of guidelines is not sufficient to control promotion [9-10].

The market size of pharmaceuticals in Bangladesh is around US$ 1.68 billion [11]. 276 companies have marketed around 27000 products in our country [12] and pharmaceutical companies conduct promotional activities to increase market share of their products. From time to time, Bangladesh formulated several policies, acts and code to promote rational use of medicine. In 1994, Code of Pharmaceutical Marketing Practices (CPMP) was approved to promote and support continuous development of and strict adherence to the ethical principles of marketing of pharmaceutical products [13-14]. The present study has attempted to explore current regulatory documents regarding pharmaceutical promotion and compare with global documents in this particular issue. For analyzing national regulatory documents of Bangladesh regarding pharmaceutical promotion, following related policy and regulatory documents of Bangladesh were reviewed- National Drug Policy 1982, The Drug (Control) Ordinance, 1982, National Drug Policy, 2005, The Consumer Rights Protection Act, 2009, and Code of Pharmaceutical Marketing Practice, 1994. Later, During selection of national guidelines, two countries from high income group, two from the middle income group and two from the low income group were selected. National guidelines/ code of conducts of Australia (Medicines Australia 'Code of Conduct'), United Kingdom (ABPI 'Code of Practice for Pharmaceutical Industry'), Malaysia (PhAMa 'Code of Conduct'), India ('Uniform Code of Pharmaceuticals Marketing Practices'), Nepal (Guidelines on Ethical Promotion of Medicine) and Zimbabwe (Advertising Guidelines) were analyzed and reviewed in order to evaluate status of ambiguity and inadequacy of the existing Code of Pharmaceutical Marketing Practices of Bangladesh.

**Regulation of Pharmaceutical Promotion Around the World:** IFPMA published 'IFPMA Code of Pharmaceutical Marketing' in 1981 to regulate the promotional activity of pharmaceutical industries, and extensively revised in 2006 and 2012 [6]. This code is now considered as an international model for effective development of local codes. It is a requirement of IFPMA membership that the member associations acknowledge and adhere to the conditions of the IFPMA Code. In addition, they need to adopt codes that meet local requirements, which are consistent with and as comprehensive as the IFPMA Code [15].

WHO published 'Ethical Criteria for Medicinal Drug Promotion' in 1988 [7]. And this was intended as guidance for countries to use when developing their regulations and practices around medicinal drug promotion. The document is still used by regulators, governments, and academics as a yardstick for measuring the acceptability of promotional activities. WHO guidance document is particularly playing important role in countries where local regulation is absent or insufficient [5].

In most of the countries, pharmaceutical promotion is regulated through self-

regulation approach. Under self-regulation, government is the legislative authority to control promotion in some or all aspects along with national industry associations. These associations voluntarily formulate their own codes or guidelines, and the members of the associations are obliged to follow these. In this approach, monitoring of promotion has been maintained by the complaint system, from both physicians and competing companies, and publication of complains. Issuing a corrective advertisement, withdrawal of promotional materials, fines or expulsion from the association and publication of sanctions are used to control promotional activities. Government can take steps, only if serious violations occur. Australia, Sweden and the UK are examples of self-regulation approach [5], though the success of this approach is not out of question [16].

In Australia, promotional activities of pharmaceutical industry were strictly controlled and regulated by both government and national industry association, and industries were repeatedly fined for violations of code of conduct [17].

The Pharmaceutical Association of Malaysia (PhAMA) adopted "Code of Pharmaceutical Marketing Practices" in 1978, for self-regulation of pharmaceutical marketing and promotion in Malaysia. This includes separate codes of conduct for prescription and OTC products. The codes has been amended from time to time [18], though the effect of this regulatory framework was never evaluated.

In India, Department of Pharmaceuticals introduced "Uniform Code of Pharmaceutical Marketing Practices" in 2014 to detect and stop malpractices in pharmaceutical marketing and/or promotion, which includes provision prohibiting gift to physicians [19]. Beforehand, Organization of Pharmaceutical Producers of India (OPPI) introduced "Code of Pharmaceutical Practices", which was the guideline for pharmaceutical industry [15].

Nepal is a country where domestic pharmaceutical companies share only 35% of the total market and remaining portion is met through import. In 2007, Department of Drug Administration (DDA) of Nepal introduced "Guidelines on Ethical Promotion of Medicine" to encourage ethical promotion of medicine. The same department is authorized to regulate promotion and/or advertising of medicines. Yet, there is no national code of conduct concerning advertising and promotion of medicines formulated by the industries [20]. Nevertheless, Harper et al. [21] revealed significant presence of unethical promotion in Nepal.

In Zimbabwe, 14 domestic pharmaceutical manufacturers share 47% of market. Transnational (TNCs) innovator and generic competitor companies have no direct presence in Zimbabwe. They are all represented either by distributors or wholesalers and there are 104 pharmaceutical wholesalers who are permitted to import. Medicine Control Authority of Zimbabwe (MCAZ) introduced "Advertising Guidelines for Medicine" in 2011, which includes promotional materials but does not mention anything about other forms of promotional activities [22]. Another related regulatory guideline named

"Medicine and Allied Substances Control Act" was found ineffective to control and regulate drug advertisements [23].

The USA and France are among the few countries where government directly regulates pharmaceutical promotion. US-FDA by its Office of Prescription Drug Promotion (OPDP) regulates pharmaceutical promotion. OPDP regulates and monitors promotional activities. Also, by administering OPDP Bad Ad Program, OPDP educate healthcare providers to recognize misleading promotion. Enforcement was done by notices of violation, warning letters injunction, consent decree seizures and criminal action, civil and monetary penalties [24]. The big pharmaceuticals were repeatedly fined and penalized in billions for illegal off-label marketing of drugs and paying kickbacks to healthcare professionals to encourage them to prescribe promoted drugs. But the financial penalties were actually a small amount in comparison to company profits [25].Later on, an act named 'the Sunshine Act' was passed in 2010 as part of the "Affordable Care Act" that requires manufacturers of drugs, devices, biologicals and medical supplies to report annually every payment and other transfers of value to physicians and teaching hospitals [26]. A project supported by ProPublica provided a unique opportunity for every citizen of the USA to know their doctor's financial relationship with industry through a program titled 'Dollars for Docs' [27].

**Regulation of Pharmaceutical Promotion in Bangladesh**: Current laws and the Code of Pharmaceutical Marketing Practices provide the regulatory framework for the control of advertising and promotion of medicines in Bangladesh. Code of Pharmaceutical Marketing Practice (CPMP) was developed according to global standards including the WHO Ethical Criteria for Medicinal Drug Promotion, IFPMA Code of Pharmaceutical Marketing Practices, and ABPI Code of Practice for the Pharmaceutical Industry [13]. Studies [14, 28] found that the Code of Pharmaceutical Marketing Practices (CPMP) was ineffective in improving the quality of information provided in advertisement published in medical journal as well as in pharmaceutical promotional literature. In 2010, WHO and later on, USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program explored the regulatory framework for pharmaceutical promotion, specified the weaknesses and recommended some changes [13], [29].

**Table I. Review Regulatory Documents of Bangladesh Related to Pharmaceutical Promotion**

| Indicators | National Drug Policy 1982 | Drug Control Ordinance 1982 | National Drug Policy 2005 | Consumer Protection Act 2009 | Code of Pharmaceutical Marketing Practice 1994 |
|---|---|---|---|---|---|
| Form of promotion | Not stated | Not stated | Not stated | Not stated | Clearly defined |
| Monitoring of promotion | Not stated | Not stated | Not stated | Not stated | Not stated |
| Interpretation and implementation procedure for regulation of promotion | Not stated | Clearly defined | Not stated | Not stated | Not stated |

**Table II. Structured Review of National guidelines and Code of Conducts about 'background information' and 'form of promotion'**

| Points | Bangladesh | Australia | UK | India | Malaysia | Nepal | Zimbabwe |
|---|---|---|---|---|---|---|---|
| **A.Background information** | | | | | | | |
| i)Edition | 1 | 18 | 16 | 3 | 19 | 1 | 1 |
| iii)Types of regulation | Govt. | Self | Self | Self | Self | Govt. | Govt. |
| iii)Regulatory body | DGDA | TGA, MA | MHRA, ABPI | CDSCO, OPPI | MAB, PhAMA | DDA | MCAZ |
| **B.Form of promotion** | | | | | | | |
| **i)Printed promotional materials** | | | | | | | |
| a)Standards of information | Clearly defined | Clearly defined | Clearly defined | Clearly defined | Clearly defined | Clearly defined | Clearly defined |
| b)Text/ Font size | Ambiguously defined | Clearly defined | Not mentioned | Not mentioned | Clearly defined | Not mentioned | Not mentioned |
| **ii)Gift** | | | | | | | |
| a)Types of gift allowed | Clearly defined | Clearly defined | Clearly defined | Clearly defined | Clearly defined | Not mentioned | Not mentioned |
| b)Types of gift prohibited | Not mentioned | Clearly defined | Clearly defined | Not mentioned | Clearly defined | Not mentioned | Not mentioned |
| c)Monetary value of gift | Not mentioned | Not mentioned | Clearly defined | Not mentioned | Clearly defined | Not mentioned | Not mentioned |
| **iii)Sample** | | | | | | | |
| Quantity of sample | Not mentioned | Clearly defined | Clearly defined | Not mentioned | Not mentioned | Not mentioned | Not mentioned |
| **iv)Symposia & other scientific meeting** | Not mentioned | Clearly defined | Clearly defined | Clearly defined (prohibited) | Clearly defined | Clearly defined | Not mentioned |
| **v)Hospitality** | Not mentioned | Clearly defined | Clearly defined | Clearly defined (prohibited | Clearly defined | Clearly defined | Not mentioned |

**ABPI:** The Association of the British Pharmaceutical Industry; **CDSCO:** Central Drug Standard Control Organization; **DDA:** Department of Drug Administration; **DGDA:** Directorate General of Drug Administration; **MA:** Medicine Australia; **MAB:** Malaysia Advertisement Board; **MCAZ:** Medicine Control Authority of Zimbabwe; **MHRA**: Medicines and Healthcare Products Regulatory Agency; **OPPI:** Organization of Pharmaceutical Producers of India; **PhAMA:** Pharmaceutical Association of Malaysia; **TGA:** Therapeutic Good Australia**.**

**Table III. Structured Review of National guidelines and Code of Conducts about 'systems required for monitoring of promotion' and 'systems required for enforcement of regulation of promotion'**

| Points | Bangladesh | Australia | UK | India | Malaysia | Nepal | Zimbabwe |
|---|---|---|---|---|---|---|---|
| **C.Systems required for monitoring of promotion** | | | | | | | |
| i) Governmental system for monitoring | Not mentioned | Not mentioned | Not mentioned | Not mentioned | Not mentioned | Not mentioned | Not mentioned |
| ii)Mechanism of monitoring | Not mentioned | Clearly defined | Clearly defined | Not mentioned | Not mentioned | Not mentioned | Not mentioned |
| iii)Body responsible for monitoring | Not mentioned | Clearly defined | Clearly defined | Not mentioned | Not mentioned | Not mentioned | Not mentioned |
| iv)Complaint system | Not mentioned | Clearly defined | Clearly defined | Clearly defined | Clearly defined | Not mentioned | Clearly defined |
| V)Publications of complaints | Not mentioned | Clearly defined | Clearly defined | Clearly defined | Clearly defined | Not mentioned | Clearly defined |
| **D.Systems required for enforcement and regulation of promotion** | | | | | | | |
| i)Responsible body for enforcing and regulation of promotion | Clearly defined | Clearly defined | Clearly defined | Clearly defined | Clearly defined | Clearly defined | Clearly defined |
| ii)Sanctions | Not mentioned | Clearly defined | Clearly defined | Clearly defined | Clearly defined | Not mentioned | Not mentioned |
| iii)Publication of sanctions | Not mentioned | Clearly defined | Clearly defined | Clearly defined | Clearly defined | Not mentioned | Not mentioned |
| iv)Appeal mechanism | Not mentioned | Clearly defined | Clearly defined | Clearly defined | Clearly defined | Not mentioned | Not mentioned |

**Policy and Regulatory Documents of Bangldesh in Context with Global documents:** In 2011, the Medicines Transparency Alliance (MeTA) and the Health Action International (HAI) global Program, under the guidance of an advisory group of international experts, has developed a methodology to help countries gain an overview of the national regulatory framework regarding medicines promotion, and a 'data compilation tool' has been developed [30]. This data compilation tool was divided into four categories (background information, scope of

regulation, monitoring of promotion and enforcing medicine promotion). As these national guidelines and code of conducts were drafted on the socio-economic and cultural background as well as setting and market size of pharmaceutical industry of those particular countries, selected indicators (background information, forms of promotion, systems required for monitoring and regulation for enforcement) of HAI/MeTA 'data compilation tool' were used to review them. And findings were categorized as 'not mentioned', 'ambiguous' and 'clearly defined'.

In Bangladesh, Code of Pharmaceutical Marketing Practices is the only regulatory document to address pharmaceutical promotion although interpretation and implementation procedure was only clearly defined in Drug Control Ordinance 1982 (Table I). Countries like Australia, Malaysia and UK regularly updated their regulatory framework, whereas CPMP of Bangladesh was never updated after introduction (Table II). A recent study revealed that majority of the physicians and medical representatives of Bangladesh are not aware about the existing CPMP, and the conflicting relationship between physician and pharmaceutical industry was labeled as 'unholy alliances' [31]. The national guidelines have tried to guide or regulate pharmaceutical promotion, which is an indirect acknowledgment about it's detrimental influence. The studied guidelines demonstrate that there was effort to regulate promotion and bring those activities under the framework of scientific justification. This study revealed that the regulatory measures of different countries particularly differ in enforcement aspects (Table III). Among the documents, presence of clear directive for punishment in case of unethical promotion varies greatly among countries. In countries like Australia and UK, in every occasion, there are some instructions and provisions in the documents that prohibit the industry from doing certain activities and there are definite punishments mentioned in the laws and regulations in case of violations. In addition to those laws, different countries adopted special measures like Sunshine Act in USA [32] and voluntary reporting by competing companies and healthcare professionals or consumers in Australia. Moreover, the monitoring approaches are found to be effective because of existence of supporting laws to ensure the punishment for violations [33].

The present study found that the frameworks of Bangladesh, India, Malaysia, Nepal, and Zimbabwe only mentioned the areas but the authority of the entrusted agency after identifying any violation was not defined (Table II and Table III). This deviation is crucial because whether there is commitment of the relevant bodies stated in the document or not, whether specific activities are referred as prohibited or not, whether some appropriate criteria are mentioned in the document or not, more importantly whether the violating industry will be punished or not, and finally whether the regulatory authority is authorized to punish the case of violation are the key determinant for the regulation of pharmaceutical promotion in any country. If these are not mentioned clearly in the regulatory documents and are not supported by law, actually these documents are not that

effective [34]. Possibly, this incompleteness of regulatory frameworks responsible for weaker enforcement.

**Conclusion and Recommendations**: The regulatory frameworks to control pharmaceutical promotion vary to a great extent from country to country. Clearly defined prohibitions, specific legal provisions for violations and entrusted agency with defined authority to punish in case of violations are absent in the related Code of Bangladesh. Code of Pharmaceutical Marketing Practices of Bangladesh requires updating which should include the limit of acceptance of gift or other support from the industry along with specific prohibitions and legal provision of punishments for violations.

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1st author conceive the idea, done literature review and wrote the manuscript. 2nd author guide to the conception of idea, manuscript writing and check the manuscript meticulously