

A Research paper on

***STUDY OF DRUG PROMOTIONAL BROCHURE AS
A SOURCE OF DRUG INFORMATION
IN
BANGLADESH***

Submitted by

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Table of Content:

Chapter 1:	Pages
Introduction.....	7
Two organizations control pharmacy practice in Bangladesh.....	8
Current scenario of Bangladesh pharma market.....	8
Top 10 pharma companies of Bangladesh.....	10
Recent Exports by Some Bangladeshi Pharmaceutical companies.....	12
Drug promotion.....	13
Evidence of Failure to Give Proper Information.....	16
WHO Recommendation for Drug Advertisement.....	16
Chapter 2	
Literature Review.....	19
Chapter 3	
Drug Promotional Brochures.....	23
Types of drug promotional brochures.....	24
Objectives of Drug Promotional brochures.....	28
Criteria for Drug Promotional Brochures.....	30
What information should be in a drug promotional brochure?	32
References in advertisements.....	35
Pictures and images in advertisements.....	38
Chapter 4	
Data collection and Data Analysis.....	42
Results.....	43
Recommendation.....	57
DISCUSSION.....	61
References.....	63

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CERTIFICATE

This is to certify that the thesis “Drug Promotional Brochure As a Source of Drug Information In Bangladesh” submitted to the Department of Pharmacy, East West University, Dhaka in partial fulfillment to the requirements for the degree of Bachelor of Pharmacy (B.Pharm) was carried out by Md. Saifullah Shikder (ID: 2005-2-70-069) under our guidance and supervision and that no part of the thesis has been submitted for any other degree. We further certify that all the sources of information availed of this connection is duly acknowledge.

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Study of Drug Promotional Brochure
As a Source of Drug Information
In
Bangladesh

*This thesis paper is dedicated to my beloved parents &
All freedom fighters of Bangladesh*

Abstract

Objective: A major marketing technique used by pharmaceutical companies is direct-to-physician marketing. This form of marketing frequently employs promotional marketing brochures, based on clinical research, which may influence how a physician prescribes medicines. This study was aimed to evaluate collected drug promotional brochure as a source of drug information in Bangladesh: a critical analysis of the brochures for the authenticity of information. The World Health Organization (WHO) criteria for ethical drug promotion are used in this study.

Methods: The study was conducted with 98 different promotional brochures. This promotional brochure was collected from Square Pharmaceutical Ltd & Beximco Pharma Ltd. 72 promotional brochure was collected from Square pharmaceutical Ltd and the remaining 26 brochures were collected from Beximco Pharmaceutical Ltd. Both pharmaceuticals are the leading pharmaceutical company in Bangladesh.

Summary of the results: The findings from the present study show that the quality of reporting of various parameters of quantitative research in drug promotional literature distributed by pharmaceutical companies is poor. On the basis of the information available in the promotional literature, it is very difficult for a physician to assess the validity of the study and that may lead to inappropriate prescribing. None of the promotional brochures fulfilled all WHO criteria. Because the major side affects, placebo study, presence of reference, mechanism of action- all these things was not present in a brochure. In addition from this study it is clear that antibiotics are used highly in our country because antibiotics contain 25% of total brochures. Beside I also find a result on using different dosages form

Conclusion: Pharmaceutical industries did not follow the WHO guidelines while promoting their products, thus aiming to satisfying their commercial motive rather than fulfill the education aspect of promotion.

CHAPTER 1

INTRODUCTION

In Bangladesh the pharmaceutical sector is one of the most developed hi-tech sectors within the country's economy. After the promulgation of Drug Control Ordinance - 1982, the development of this sector was accelerated. The industry is the second highest contributor to the national exchequer after garments, and it is the largest white-collar intensive employment sector of the country. There are about 450 generics registered in Bangladesh. Out of these 450 generics, 117 are in the controlled category i.e. in the essential drug list. The remaining 333 generics are in the decontrolled category, The total number of brands /items that are registered in Bangladesh is currently estimated to be 5,300, while the total number of dosage forms and strengths are 8,300. Bangladesh pharmaceutical industry is mainly dominated by domestic manufacturers. Of the total pharmaceutical market of Bangladesh, the local companies are enjoying a market share reaching around 80%, while the MNCs are having a market share of 20%.

The professional knowledge, thoughts and innovative ideas of the pharmaceutical professionals working in this sector are the key factors for these developments. Due to recent development of this sector it is exporting medicines to global market including European market. This sector is also providing 97% of the total medicine requirement of the local market. Leading pharmaceutical companies are expanding their business with the aim to expand export market. Recently few new industries have been established with high tech equipment's and professionals which will enhance the strength of this sector.

Some renowned companies have already entered the Highly Regulated Market and got the UK MHRA, EU, TGA Australia and GCC approval and some are in the process to get the USFDA & UK MHRA approval. Through this accreditation these companies will be able to export medicine and through contract manufacturing agreement.

(Success Story of Generic Pharmaceutical Industry in Bangladesh, 2011)

Two organizations control pharmacy practice in Bangladesh

1. Directorate of Drug Administration (One government) and
2. Pharmacy Council of Bangladesh (Another semi government).

The Bangladesh Pharmaceutical Society is affiliated with international organizations International Pharmaceutical Federation and Commonwealth pharmaceutical association.

(Pharmaceutical industry in Bangladesh, 2012)

CURRENT SCENARIO OF BANGLADESH PHARMA MARKET

According to Bangladesh Pharmaceuticals and Healthcare Report 2011, Bangladesh medicine sales reached Tk 7,000 crore in 2010. Business Monitor International in its latest report (2011) said Bangladesh has moved up one place to occupy the 14th position in 17 regional markets surveyed in BMIs Pharmaceutical & Healthcare Business Environment Ratings for the Asia region. Bangladesh's pharmaceutical rating is 40.2 out of 100, a figure that has changed marginally from the previous quarter but remains lower than the regional average of 53.1. Globally, Bangladesh occupies 67th position in BMIs 83 market-strong pharmaceutical universe.

The leading pharmaceutical companies in the country such as Advanced Chemical Industries (ACI) Limited, Square Pharma, GlaxoSmithKline Bangladesh Ltd, Beximco Pharmaceuticals Ltd, Eskayef Pharmaceuticals Ltd etc., now possess adequate amenities to produce tablets, capsules, injectable, liquids, suspensions, sustained release dosage forms, dry powders metered dose inhalers, sterile ophthalmic formulations, HFA, inhalers, suppositories, hormones, steroids, oncology, immunosuppressant products, nasal sprays, creams and ointments.

The major drugs commonly produced in Bangladesh include paracetamol, diclofenac, ampicillin and amoxicillin among numerous others.

In recent years, the country has achieved autonomy in large volume parenteral, some quantities of which are also exported to other countries. Imports constitute about five per cent, including finished formulations like vaccines, latest anti-diabetics and anti-cancer drugs. The industry players forecast the growth trend would take the sales volume to Tk 10,000 crore in 2011. Square, Beximco, Eskayef, Incepta and Acme are the top five manufacturers by sales and growth rate.

Beximco grew faster than other companies at a staggering 33 percent in 2010 with Tk 523 crore sales. Incepta's sales and growth rate were Tk 665 crore and 31 percent respectively,

followed by Acme's Tk 600 crore and 17 percent. Eskayef logged Tk 426 crore in sales and the growth rate was 27 percent, the third highest pace in the year.

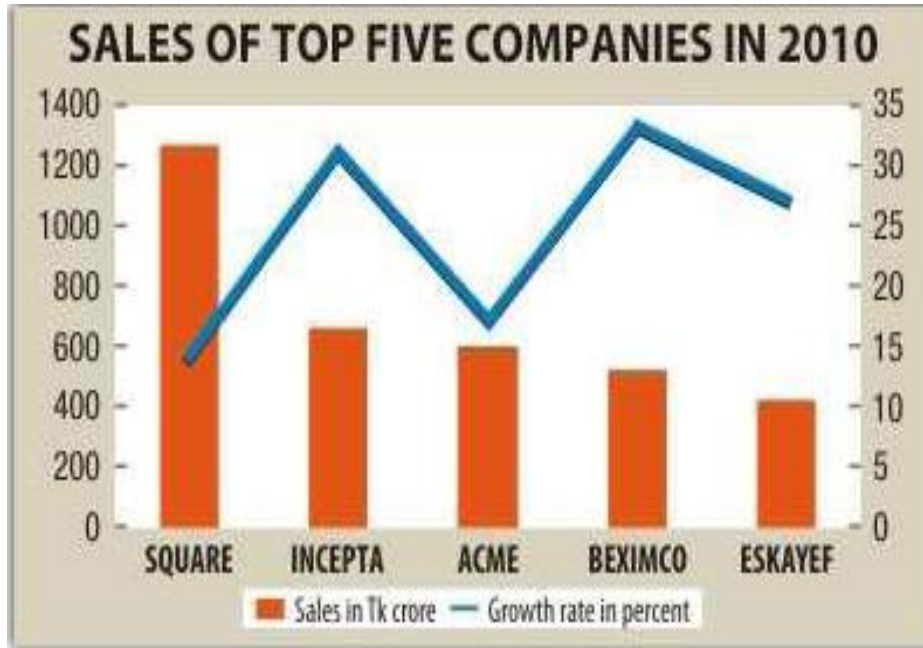


Figure 1: Sales of Top 5 Pharma Companies in 2010.

A large population and relaxation of trade related intellectual property rights (TRIPS) for least developed countries are contributing to the market growth and also increasing health consciousness, buying capacity have helped the industry grow consistently. Bangladesh has been granted permission by the World Trade Organization (WTO) to reproduce the patented products up to year 2015 as per trade related intellectual property rights (TRIPS)

TOP 10 PHARMA COMPANIES OF BANGLADESH

Of the 250 companies, top 10 companies -- Square, Beximco, Eskayef, Incepta, Acme, ACI, Opsonin, Renata, Aristopharma and Drug International take up nearly 70 percent of the total market share, according to the IMS 2008 survey.

MARKET GROWTH

Pharmaceutical exports stood at \$18.69 million in the July-November period of fiscal 2009-10, a 15.44 percent rise from the same period a year ago, according to the Export Promotion Bureau

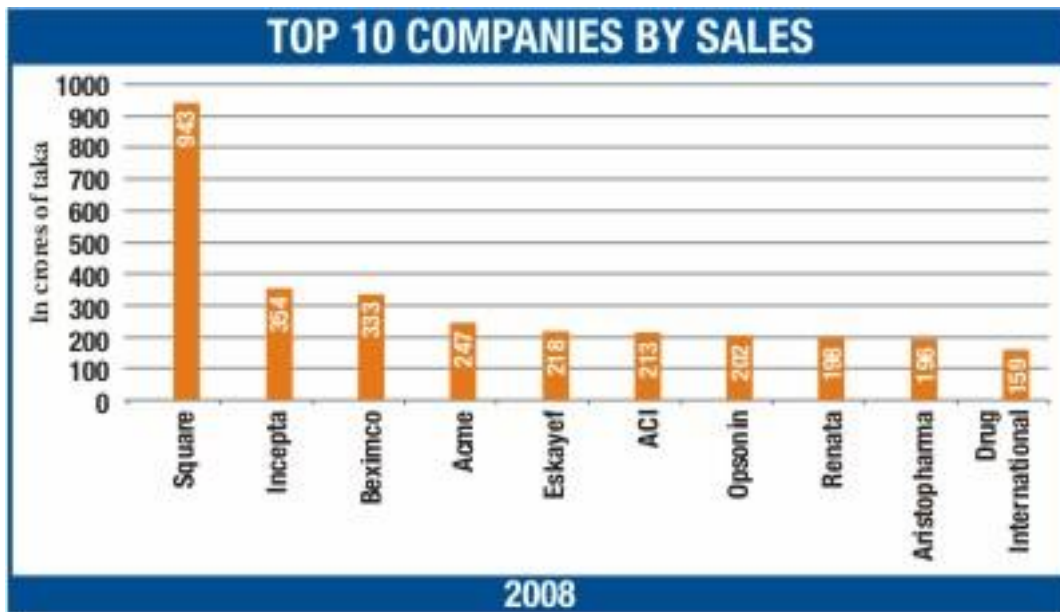
Top 10 companies by local sales

(Ranking by Intercontinental Marketing Services)

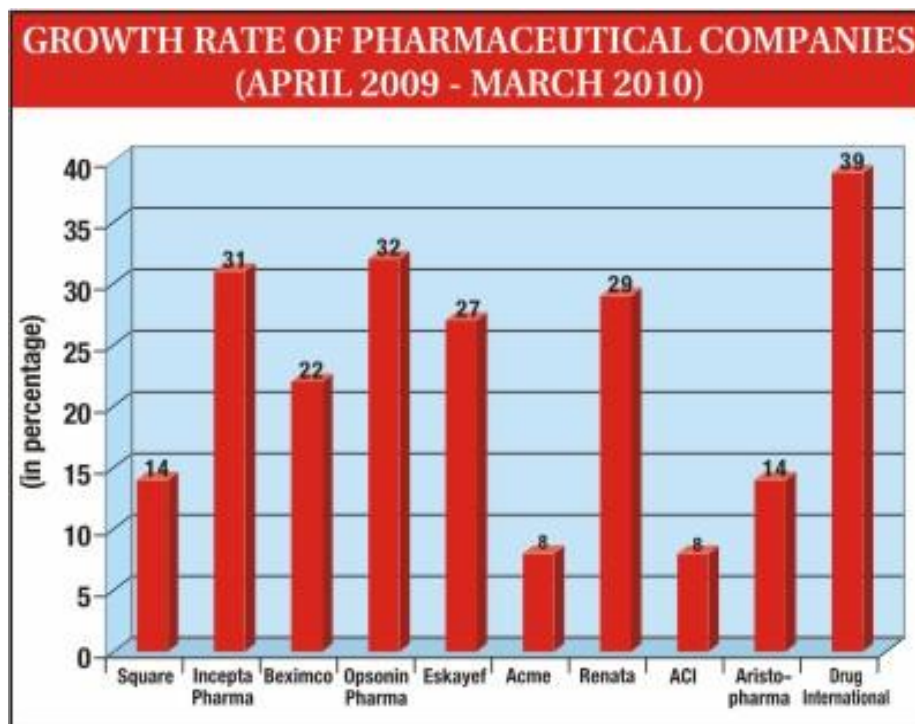
Opsonin Pharma
Eskayef Bangladesh
Drug International
Beximco Pharmaceuticals
Incepta Pharmaceuticals
Renata
Advanced Chemical Industries (ACI)
Square Pharmaceuticals
Aristopharma
ACME Laboratories

STAR GRAPHICS

Top medicine makers recorded robust growth last year at an average 25 percent, riding on people's growing health awareness and purchasing power, according to the market players. Bangladesh medicine sales reached Tk 3,700 crore three years ago, which nearly doubled to Tk 7,000 crore in 2010. The industry players forecast the growth trend would take the sales volume to Tk 10,000 crore in 2011.



Annual turnover from retail drugs sales was Tk 4,701.63 crore in 2008, nearly 7 percent rise over the figure a year earlier, according to IMS (information on medical statistics) data. The market size was Tk 4,075 crore in 2007.



According to a report published by IMS Health, retail sales of pharmaceutical products grew 18 per cent in the 12 months to March 2010, while local sales stood at Tk 57.8 billion for the

period. Export earnings from pharmaceuticals totaled \$44.27 million in the last fiscal surpassing \$ 40.97 million earned in 2009-10 fiscal, Export Promotion Bureau (EPB) data shows.

Growth in Bangladesh's pharmaceutical sector has been attributed to growing health consciousness in both urban and rural areas, advanced manufacturing processes and new investments that have helped boost local sales.

(The Daily Star, 2009)

Recent Exports by Some Bangladeshi Pharmaceutical companies

Several pharmaceutical manufacturers have already made huge investments in their new state of art manufacturing facilities for entering highly regulated overseas markets like USA and Europe. The export value of pharmaceuticals, though small, is growing at 50 per cent per year. Exports increased from \$82,00000 in 2004 to \$283,00000 in 2007 and expanded further in last two of years. The export destinations have now risen from 37 to 72 countries during the period.

Table 1: Recent Exports by Some Bangladeshi Pharmaceutical companies.

Company	Export (USD)	Year of Export
Novartis / Sandoz	12,820,162	2004-2005
Beximco Pharmaceuticals	1,400,000	2004
Square Pharmaceuticals	1,200,000	2004
Jams Pharmaceuticals	633,721	2000-2004
Jayson Pharmaceuticals	626,546	2004
The Acme Laboratory Co	600,000	2004
Eskayef Bangladesh	331,876	2004
Aristopharma	305,648	July 2004 – June 2005
Renata	281,788	2004
Navana Pharmaceuticals	240,175	Sept 2003 – June 2005
Sanofi Aventis	223,999	2004
ACI	156,392	2004
Essential Drug Co	124,687	2004

Globe Pharmaceuticals	68,410	2005-2006
Opsonin Pharmaceuticals	34,109	2004

(Pharmaceutical Opportunities in Bangladesh, 2008)

Drug promotion

Pharmaceutical companies are in the business of developing and selling new drugs. These are accepted in health care system through health care professionals and its availability is of little value unless the prescriber is aware of its existence and has scientific information to use it effectively. Pharmaceutical promotion is a persuasive communication and the major marketing technique of pharmaceutical companies is direct to physician marketing. Physicians are contacted by medical representatives, presented with sample drug, token gifts, and reminder articles and also targeted through sponsored continued medical education, advertisements in the medical journals, etc. One of the well-known promotional activities of pharmaceutical industries is to produce advertising brochures which at times are inaccurate and of poor educational value. These promotional activities create the potential for inappropriate prescribing practice by influencing physicians prescribing behavior without necessarily benefiting the patients but contributes to increased health care costs.

Drug promotion has an important bearing on the rational use of drugs; on drug price-control mechanisms, the manufacture, availability and use of essential drugs, on equity of drug distribution and the cost of health care—all making it a central public health issue.

WHO defines drug promotion as

'all informational and persuasive activities by manufacturers and distributors to induce/influence the sale and use of medicinal drugs.'

(Unethical Drug Promotion, 2007)

The promotion of medicines is very influential and needs to be carefully controlled. The pharmaceutical industry differs from other industries in that its products directly affect the health

of patients. The sale of these medicines is strictly controlled through market authorization (registration), prescribing and dispensing regulations. Ethical promotion of medicines is

important in order to ensure that medicines are prescribed and used in a rational way. Promotional activities that do not comply with ethical criteria for medicinal pharmaceutical promotion are an important factor contributing to inappropriate overuse and unnecessary costs. In the USA, the promotion of medicines is regulated by the government via its Food and Drug Administration, but in most other industrialized countries the promotion of medicines is still controlled by self-regulatory mechanisms, based on codes of practice.

(Prof. H.G.M. Leufkens, 2006-2007)



Clip boxes (Risdon)



Stapler machine (Ciprocin)



Pin remover (Calbeta)



Punch machine (GabaTIN)



Show piece (Myrica)

Figure : Promotional desk products

Evidence of Failure to Give Proper Information

Nobhojit Roy, Head of the Department of Surgery at BARC Hospital in Mumbai have examined three studies comparing advertisements in India with those in other countries and concluded in 2004 that: “Drug advertisements in Indian medical journals contain less information on safety and clinical pharmacology than their American and British counterparts do”. In a similar study, Niyada Kiatying-Angsulee of the Social Pharmacy Research Unit, Chulalongkorn University, Bangkok and colleagues examined 256 advertisements targeting the general public via billboards and radio. Their findings show that 79 were from multinational companies and 38 were for prescription only drugs despite such advertising being illegal in Thailand. In addition they examined doctor-directed promotions, which included 207 advertisements with health claims. The analysis includes:

- Generic names of drugs are not revealed in more than 10% of advertisements.
- Only 22.7% disclosed any adverse effects.
- Just 25.1% provided any precautionary information.
- Only 51.7% cited any references.

So it is obvious to raise questions about the quality of reporting in the promotional brochure.

WHO Recommendation for Drug Advertisement

The WHO Criteria clearly states that advertisements in all forms to physicians and health related professionals should be fully consistent with the approved scientific data sheet for the drug concerned or other source of information with similar content. Moreover, advertisements that make a promotional claim should at least contain summary of scientific information. A brief review of the WHO mentioned information needed to be including in Promotional literature is given below:

- The name(s) of the active ingredient(s) using either international nonproprietary names (INN) or the approved generic name of the drug.
- The brand name
- Amount of active ingredient(s) per dose
- Other ingredients known to cause problems, i.e. adjuvant
- Approved therapeutic uses
- Dosage form or dosage schedule
- Name and address of manufacturer or distributor
- Safety information including side effects and major adverse drug reactions, precautions, contraindications and warnings, and major drug interactions
- Reference to scientific literature as appropriate

Also the International Federation of Pharmaceutical Manufacturers Association (IFPMA) Code of Pharmaceutical Marketing Practices (revised in 2006) sets out standards of promotional material which should be consistent with product information, accurate, not misleading and reflect the evidence clearly.

(WHO, 2009)

CHAPTER 2

Literature Review

Pharmaceutical companies are in the business of developing and selling new drugs. They are the only information providers to the health professionals in Bangladesh. These are accepted in health care system through health care professionals, and its availability is of little value unless the prescriber is aware of its existence and has scientific information to use it effectively. Pharmaceutical promotion is a persuasive communication and the major marketing technique of pharmaceutical companies is “direct to physician marketing.” Physicians are contacted by medical representatives, presented with sample drugs, token gifts, reminder articles and also targeted through sponsored continued medical education, advertisements in the medical journals, etc. One of the well-known promotional activities of pharmaceutical industries is to produce advertising brochures 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 benefiting the patients but contributes to increased health care costs.

There has been a tremendous increase in the number of new and generic drugs coming into the market. The busy practitioner obtains the information from various sources, of which promotional literature forms an important source. The promotional literature provided by the pharmaceutical companies cannot be entirely relied upon; moreover, very few physicians are equipped with the skills of critically appraising it. There are about 450 generics/substances registered in Bangladesh. One hundred and twenty-two new and generic drugs were approved by the FDA in October 2007. The number of drugs entering the market is growing at an alarming rate.^[3] In short there is an information explosion. Thus it is almost impossible for a busy medical professional to study and compile the most current and detailed information. During their years of formal training, medical students and residents are exposed to their intensive teaching experiences designed specifically to produce clinicians whose skills reflect current best knowledge and practice. But once in practice, they are essentially on their own and face the serious challenge of keeping their knowledge, skills, and performance up-to-date, in the midst of an increasingly hectic professional life.

(Stimson GV. 1975)

Few studies describe regulations and guidelines about printed and broadcast promotional material and how they are monitored in different countries. Many studies shows that printed advertisements do not meet regulations and guidelines in force in various countries. Many

studies show high levels of non-compliance with codes of practice and guidelines about promotional material, indicating that these are poor ways of controlling promotion

An Indian journals scenario was, none of the promotional literature fulfilled all WHO criteria. Majority (92%) brochures claimed about the efficacy of product and a few about safety (37%). Out of 1003 references given in support of various claims, 84.4% were from journals and only 28.5% were validly presented researchers. Brochures presenting irrelevant picture were 41.3%, whereas brief prescription information of the promoted drug was given only by 8.8% brochures.

(Smita N Mali, 2010)

In a Pakistani journal it is observed that 345 distinct advertisements covering 182 drugs from different manufacturers were critically analyzed for information content. Sixty two out of 345 (18%) of the reviewed advertisements were adjudged to be misleading / unjustifiable, which were again classified as, exaggerated (32%), ambiguous (21%), false (26%), and controversial (21%). The primary source of information (approximately 78%) about the newly launched drugs for the GPs was found to be the pharmaceutical representatives followed by hospital doctors (5%) and colleagues (5%). Furthermore, 110 (90%) GPs were of the view that the drug promotion has definitely an influence on their prescribing pattern.

(Dileep Kumar Rohraa, 2006)

A Canadian report looked at how often magazine advertisements for non-prescription drugs complied with regulatory requirements. This is interesting because these advertisements are not subject to mandatory pre-publication clearance, and are monitored by a complaints-only system. The study found an extremely high level of non-compliance with the requirements. Of the 51 advertisements only 37% complied fully, and 39% contained major violations.

(Loke TW, 2002)

In South Asian subcontinent the scenario is very different; a very little work has been done evaluating the promotional brochure. Studies regarding the promotional material have been done much in India comparing with other countries on this continent. It is hard to believe only a single work has been done on this very important issue in Bangladesh. The paper was read out, being inspired and Understanding the importance of this topic the research was done on this issue.

(Islam MS, et al., 2008)

CHAPTER 3

Drug Promotional Brochures

Drug promotional brochures mean those informational and marketing materials provided by a pharmaceutical company to inform the physicians about their product. The purpose of drug promotional brochures is to induce the prescribing, sales or use. It includes the activities of representatives and all other aspects of sales promotion in whatever form such as brochures, journals and direct mail advertisings etc. 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.

(Villanueva, P., Peiró, 1996)

As promotion of drug product can change prescribing behaviors of the health professionals, the messages of promotion should be factual, evidence-based, unambiguous and balanced. 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. Health professionals are still provided with grossly exaggerated claims all over the world. As a major promotional technique of direct-to-physician, pharmaceutical companies frequently employ promotional brochures, based on different types of clinical studies. But these promotional brochures make immoral use of scientific studies. Information in these materials is often taken from disputable clinical studies. Printed promotional materials will contain encompassing integrated information in the form of a full advertisement published in a periodical with the abovementioned characteristics they shall contain the following information:

- Commercial name of the drug
- Name of the active substance or approved generic names
- Amount of the active substances in its composition
- Therapeutically classification
- At least one approved indication
- Mode of utilization and dosage
- Major side effect and interactions
- Method of administration

(Lexchin, J. 1999).

Types of drug promotional brochures

The following resources are considered to be the essential pharmaceutical marketing materials.

1. Detail Aid: The detail aid is the “brochure” that pharmaceutical sales representatives use to promote a drug to the physician or health care professional. This is the foundation piece for the marketing campaign of the drug and contains the core messages and inherently reveals the product’s market position. The detail aid typically ranges from 4 to 26 pages and is usually 9" x 12".

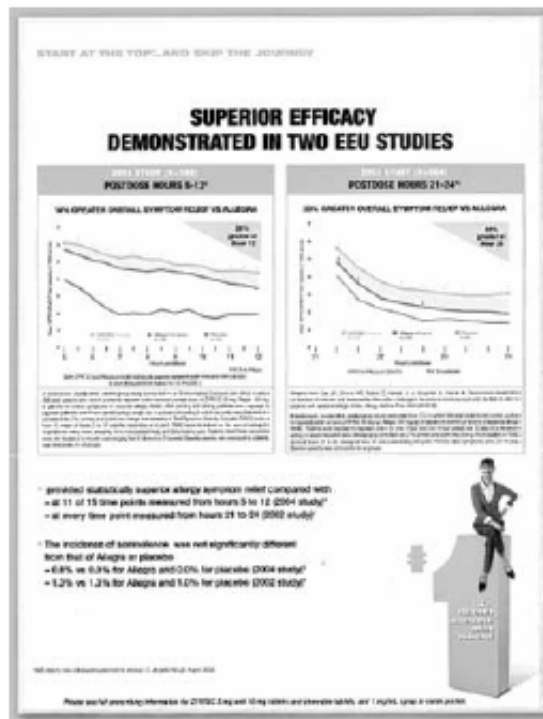


Fig: Detail Aid

2. Slim Jim: The slim Jim is a “slimmer” version of the detail aid, to make it easier for sales representatives to carry. The content of a slim Jim is identical to that of the detail aid. Another reason for the slimmer dimensions (4" x 9") is to facilitate the representative flipping through the piece while conversing with the doctor (this could be accomplished with 1 hand rather than 2). Likewise, the dimensions make it easy to fit into a doctor’s coat pocket, should the material be left behind. Some companies may produce a slim Jim as a “leave-behind” piece, as it is not as expensive (usually 50% cheaper) as a detail aid because of its smaller size.

... in human are indolent and respond poorly to treatment.¹

The most usual form of fungal infection in human is superficial fungal infection, mainly caused by dermatophytes and candida.^{1,2}

SQUARE offers

Afun[®] cream
Clotrimazole BP

The reliable antifungal

Effective against both dermatophytes and candida^{2,3}

Dermatophyte infections

Tinea Corporis
Tinea Pedis
Tinea Capitis
Tinea Cruris
Tinea Faciei/Incognito
Tinea Mannum

Cure rate: 60-100%

Candidiasis

Angular Cheilitis
Interdigitalis Blastomycetia
Intertrigo
Balanitis
Paronychia

Cure rate: 80-100%

Tinea Versicolor Cure rate: 85-100%

References: 1. Clinical Medicine by P.Kumar & M. Clark, Pg. 59&2 2. Postgraduate Medicine, January 2001, Vol.-109, Pg. 117-123 3. Harrison's Principle of Internal Medicine, 13th Ed. 1994, Pg. 1186

SQUARE PHARMACEUTICALS LTD. BANGLADESH

We care for skin™

www.squarepharma.com.bd

This is circulated with the prior approval of Licensing authority (Drugs), For Medical professionals Only. ® Registered Trade Mark. SC-01/2012/JAN/pp

Fig: Slim Jim

3. File Card: The file card is has the same content as a slim Jim but is printed on 3.5"x 5" card stock. Presumably, this is for the physician to file the card away for reference at a later date.

4. Flashcard: A flashcard is a 1-page or 2-page "ad" for the drug. It is produced as either a leave-behind (with an abbreviated version of the drug's package insert on the back side) or a non-leave-behind piece. Both versions have essentially the same copy, but the non-leave-behind version usually has more advertising copy on the back side as it may or not have a package insert.

5. Bi-fold: A bi-fold is a shortened version of the detail aid that focuses on 1 aspect of the drug's marketing campaign (i.e., drug X vs. the competitor). As in the case of the flashcard, the bi-fold may or may not include the abbreviated version of the drug's package insert.

6. Tri-fold: The tri-fold is the same as a bi-fold except that it has an extra fold-out page, allowing for 6 pages of copy instead of 4.

7. Reprint Carrier/Holder: The reprint is an actual reprint of a published clinical study that yielded favorable results for manufacturer's drug. The reprint is put in a holder or carrier that can be of various forms: a 1-page front/back with a pocket on the front side and promotional messages and references on the back, or a bi-fold format with the extra 2 pages (cover and first page) used for marketing and promotional messages.

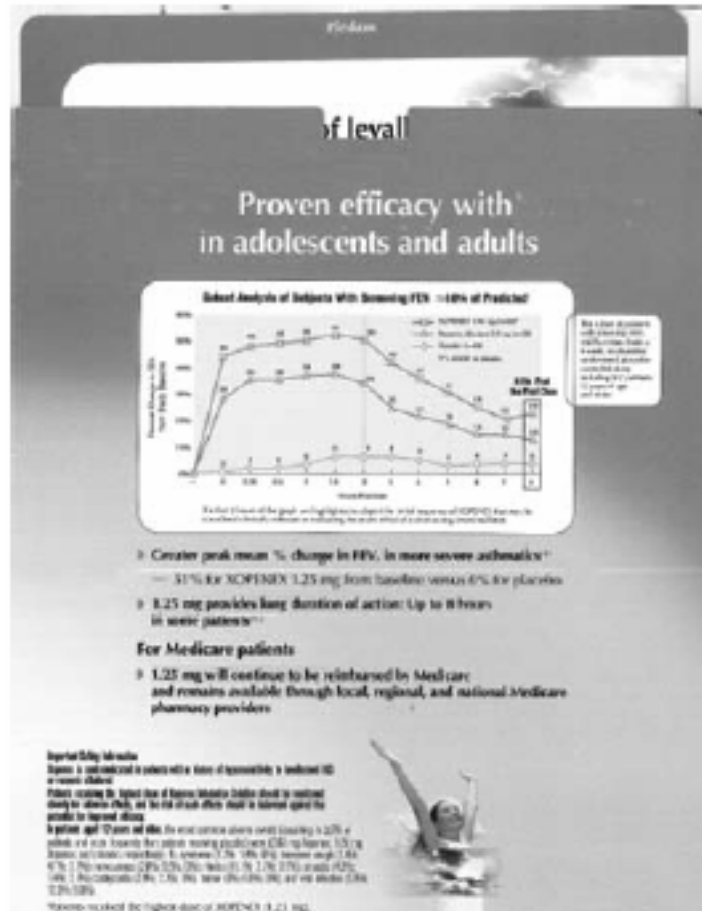


Fig: Reprint Carrier/Holder

8. Pocket Guides: As the name suggests, pocket guides are designed to fit into a physician’s coat pocket. They are typically booklets of 4-20 pages that provide information about the diagnosis and treatment of a particular disease. More than likely, information about the manufacturer’s drug is included in the treatment section of the pocket guide.

9. Disease Cards: A disease card is usually a 4" x 6" laminated card (2 sides) that graphically depicts a disease state. The purpose of a disease card is to provide a physician with an illustration to use when explaining a particular disease to a patient.

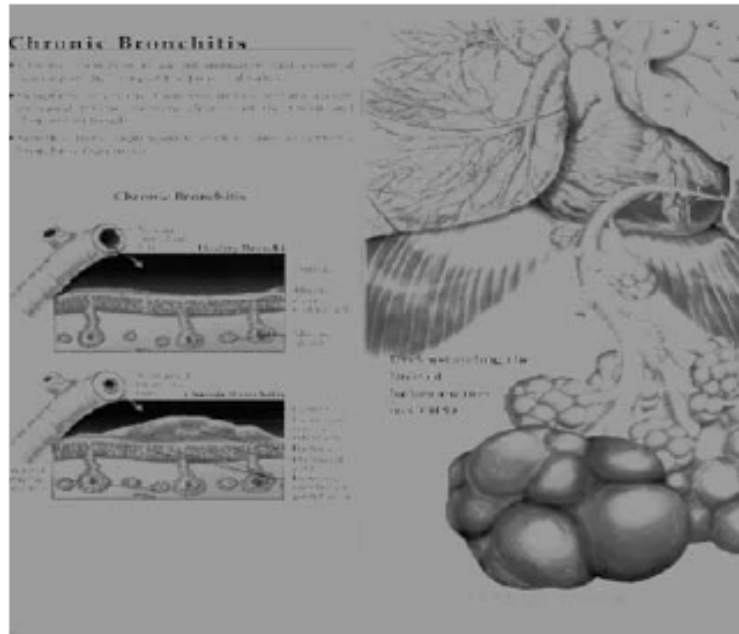


Fig: Diseases Card

10. **Dosing Cards:** Dosing cards have the same specific- captions and usage as disease cards, but the content focuses on dosage and administration information for a specific drug.

11. **Instruction Books:** Instruction books provide physicians and health care professionals with detailed instructions on how to use a certain drug. Instruction books are usually reserved for more complex drugs, devices, or biologic agents. These can range in size from a file card to a detail aid and usually come with illustrations and/or pictures on how to use/administer a certain drug.

12. **Newsletters:** Newsletters can either be scientific or promotional in nature and cover a wide range of topics. They are often published by the pharmaceutical company or a medical education company that is contracted by the pharmaceutical company. Pharmaceutical companies usually produce these for primary care physicians (general practitioners or family physicians) with the intention of educating them about a disease or a drug.

(Gray T, Hamilton CW, 2008)


Objectives of Drug Promotional brochures

Drug promotion and marketing make up a very large part of the activities of pharmaceutical companies in Bangladesh. Drug companies are the only organizations here to provide drug information to the health care providers which can be provided by the pharmaceutical promoting materials. The purpose of these pharmaceutical promoting materials is given below:

1. Drug promotional brochures are an important means of bringing drug information to health care professionals. Their primary goal is to convince clinicians to prescribe their products. These brochures often cite external documents in support of their claims.
2. The objective of drug promotional brochures is to support and encourage the improvement of health care through the rational use of medicinal substances.
3. Drug promotional brochures emphasize the importance in the public interest of providing the health professionals (doctors, pharmacists, nurses as relevant) with accurate, fair and objective information on medicinal substances.
4. Drug promotional brochures are an important means to make special offers through sales promotion and to enhance goodwill of the firm.

(Loke, T.W, 2002)

A healthy diet and lifestyle is recommended from the conception to maintain a healthy pregnancy. During pregnancy the need for folic acid & zinc is increased and even extra supplementation can stop the worst cases of pregnancy sickness.



Folic Acid Can...

- help to prevent birth defects of the brain (anencephaly) and the spinal cord (spina bifida) called neural tube defects
- help to prevent anemia
- help to prevent breast cancer, colon cancer and heart disease

Zinc promotes...

- immunity
- resistance to infection
- the growth and development of the nervous system

To fulfill the demand of Folic Acid & Zinc for women who are planning to conceive

SQUARE offers
Zifolet[®] Tablet
 Folic Acid 5 mg & Zinc 20 mg

Prevents high blood pressure in women

Folic Acid has another important health benefit which significantly reduces the risk of developing high blood pressure in women.

According to a study in the Journal of the American Medical Association, women who get lots of folic acid from both diet & supplements have less chance of developing high blood pressure than women who get very little.

Moreover,

- **Right choice before conception & first trimester of pregnancy**
- **Boosts up a healthy immune system**
- **Helps in the proper development of the fetus**
- **Effectively prevents the neural tube defects**
- **Reduces the severity and duration of common cold**

Ref: 1. www.drlera.com/health; 2. www.cdc.gov/impact/micronutrients; 3. www.schools-wikipedia.org; 4. www.healthybyheidi.com



SQUARE
 PHARMACEUTICALS LTD.
 BANGLADESH



www.squarepharma.com.bd



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Figure : A promotional brochure with Vitamin tablet

Criteria for Drug Promotional Brochures

1. All information that is used in the promotion of a product to healthcare professionals must be accurate, verifiable and sufficient so that healthcare professionals are able to form their own opinions about the therapeutic value of the product.

2. All data used in the promotion of pharmaceutical product must be accurate and verifiable. Exaggerated claims which do not follow scientific evidence must be avoided at all times. The statistical significance of scientific data must be clearly indicated. The design and interpretation of certain studies must be included with the utilizing data.

3. Misleading, unverifiable or invalid data may not be used in promotions. The following instances fall within the scope of misleading promotion:

- a) Indicating that the drugs possess therapeutic and other biological properties which have not been substantiated,
- b) Providing information on the drug's composition and its other pharmaceutical properties that may be misinterpreted,
- c) Providing false or misleading information on the manufacturer of the drug and the its employees,
- d) Providing data from in vitro tests and in vivo animal experiments without indicating the results obtained from experiments on humans,
- e) Using the such activities of drugs as an indication of potency and efficacy which will make it misleading comparisons,
- f) Making price comparisons of different drugs including pharmaceutical equivalents of the same drug,
- g) Making absolute and definitive statements citing a scientifically inadequate study that is based on an insufficient sampling size and lacking in investigative detail.

4. Pharmaceutical companies should form the pharmaceutical printed promotional literature according to the WHO criteria. The criteria's of WHO are given below:

- The name of the all active ingredient using either international nonproprietary names (INN) or the approved generic name of the drug
- The brand name
- Amount of active ingredient per dose
- Other ingredients known can cause problems, i.e. adjuvant
- Approved therapeutic uses
- Dosage form or dosage schedule

- Safety information including side effects and major adverse drug reactions, precautions, contraindications, warnings and major drug interactions
- Name and address of manufacturer or distributor
- Reference to scientific literature as appropriate.

5. Graphs and tables should be presented in such a way as to give a clear, fair and balanced view of the matters and should only be included if they are relevant to the claims or comparisons being made related to the product.

6. Graphs and tables must not be used in any way which might mislead the product. It can occur due to the incompleteness of the graphs and tables.

7. Relevant human figures and photographs may be used in promotional materials subject to approval of licensing authority.

8. Promotional materials should be used within two years of its approval by the licensing authority. Otherwise fresh approval must be obtained for further use.

9. Promotional materials should not copy the devices, slogans or general layouts which are used by other companies.

10. Telephone and Telex messages must not be used for promotion of the product.

11. Doctors' names, photographs or a prominent portrait must not be used in a promotional material or in any other way by which any individual doctor may be identified. Otherwise ethical code of the medical profession will be contradicted.

(Waxman, H.A. 2004)

What information should be in a drug promotional brochure?

The Ethical Criteria for Medicinal Drug Promotion developed by the World Health Organization (WHO) suggest the types of information that, as a minimum, should be contained in a journal advertisement (WHO, 1988). The aim is to ensure that basic information needed for prescribing decisions is present. The medicine's international nonproprietary name (INN), usually the generic name, is a key piece of information that should always be included. Generic names help doctors and pharmacists identify which class a medicine belongs to and can prevent doctors from unknowingly prescribing two medicines from the same class to a patient. While advertisements from developed countries typically contain nearly all of the information listed in the box, this is not always the case in developing countries. Table 1 from a 1993 study presents the results of a survey comparing advertisements in developed and developing countries. It is obvious from examining this table that safety information is systematically ignored in advertisements from developing

countries. More recent work analyzing advertisements in India and the Russian Federation shows that they continue to leave out essential information recommended by WHO.

...is increasing day by day and creating a major challenge for the successful therapy against many bacterial infections.

Cefepime, a 4th generation injectable cephalosporin, is highly potent and effective to eliminate the pathogens commonly associated with nosocomial and community-acquired infections

SQUARE Offers



Maxpime[®]
Cefepime

Injection

500 mg IM/IV
1 gm IM/IV
2 gm IV



Maximum power in microbes elimination



- More potent than Ceftriaxone & Ceftazidime against Enterobacteriaceae
- Effective, safe & well-tolerated therapy for patients of all age groups
- US FDA approved drug for patients older than 2 months of age
- Gram-positive activity equivalent to 1st generation and Gram-negative activity equivalent to 3rd generation Cephalosporins



www.squarepharma.com.bd



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Figure : A promotional brochure with Antibiotic

The World Health Organization's Ethical Criteria recommend that the following information be included in pharmaceutical advertisements appearing in medical journals.

- Name(s) of the active ingredient(s) using either international nonproprietary name (INN) or the approved generic name of the medicine;
- Brand name;
- Content of active ingredient(s) per dosage form or regimen;
- Name of other ingredients known to cause problems;
- Approved therapeutic uses;
- Dosage form or regimen;
- Side effects and major adverse medicine reactions;
- Precautions, contraindications and warnings;
- Major interactions;
- Name and address of manufacturer or distributor;
- Reference to scientific literature as appropriate.

(WHO, 1988)

Box 1: Recommended information in drug promotional brochure

Just because each of the categories of information is present in an advertisement does not necessarily mean that the advertisement will give a complete picture of the medicine's safety and effectiveness and how to prescribe the medicine appropriately. Although advertisements in Australian journals improved during the 1980s and early 1990s, by 1992, 4% still contained unacceptable graphics, 7% had unacceptable claims and 15% had unacceptable references. In 1992, the *Annals of Internal Medicine* published an article that critically examined the scientific accuracy of over 100 pharmaceutical advertisements in 10 leading medical journals. Overall, physician and pharmacist reviewers judged that 34% should have had major revisions before being published and 28% should not have been published at all. In 1995, most Irish doctors expressed strong reservations about the quality of advertisements in Irish medical journals, with 90% believing that the advertisements were of poor educational value.

Table 1: Information in advertisements in developed and developing countries

Type of information	Percentage of advertisements containing information	
	Developed countries*	Developing countries**
Indications	89	87
Contraindications	61	28
Warnings	55	29
Side effects	64	29

References in advertisements

Advertisements should include references whenever a claim is made that reflect scientific evidence. The claim must be consistent with cited research and the research should be designed with adequate methodology. For example, effectiveness claims should generally be based on evidence from double-blind, randomized, controlled trials. It is also important for health professionals to be able to retrieve cited references, so that they can independently evaluate them. Otherwise, any limitations or inconsistencies between the evidence and the claims will remain hidden.

These are a few common problems with referencing in advertisements:

- No references are provided for claimed treatment effects;
- Reference is to company “data on file”, which is not publicly available and has not been independently reviewed;
- A poster presentation is cited; generally inadequate information is provided on methods in poster presentations to judge reported results;
- Review articles that selectively present results are cited, not original research;
- The referenced article is in a journal supplement sponsored by the manufacturer;

Esomeprazole is a Proton Pump Inhibitor (PPI), which is an effective treatment option for acid reflux disease. PPIs work by turning off many of the "acid pumps" in the stomach's acid-producing cells. This reduces the amount of acid in the stomach. In fact, for many people, one Esomeprazole tablet/capsule in a day can ensure 24-hour relief from persistent, frequent heartburn.

Esomeprazole 40 mg and 20 mg are indicated for short-term treatment (4 to 8 weeks) of -

- healing and symptomatic resolution of diagnostically confirmed Erosive Esophagitis (EE)
- heartburn and other symptoms associated with GERD.

Millions of patients have been prescribed Esomeprazole. Since the FDA first approved it in 2001, Esomeprazole has been prescribed more than 236 million times.*

*IMS NPA database, last accessed December 2010.
www.nexiumtouchpoints.com

SQUARE offers

Nexum[®]

Esomeprazole

Proven superb acid control for 24 hours

- Active Isomer of Omeprazole that eliminates the "Poor Metabolizer Effect"
- Superior to older Proton Pump Inhibitors for the management of GERD
- Only Proton Pump Inhibitor that is safe for children of 1 year and above
- The "On Demand" Proton Pump Inhibitor
- US FDA approved pregnancy category B

Available as

Nexum[®] 20 & 40 Tablet

Nexum[®] 20 & 40 Capsule

Nexum[®] 40 IV Injection



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH



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Figure : A promotional brochure with Antiulcerant

- Study results in the cited reference are inconsistent with the advertising claim;
- The study is of poor methodological quality, raising questions about the validity of the results.

Box 2: How to evaluate references in pharmaceutical advertisements

- Do citations contain all of the information necessary to identify references?
- Are all references cited retrievable including those to “data on file”?
- Are references of high methodological quality?
- Do journal references come from peer-reviewed medical or pharmacy journals?
- Did the company finance the research reported in the reference?

Box 3: How to evaluate the text in pharmaceutical advertisements

- Are generic names used as frequently as brand names and is the type the same size as that used for the brand name?
- Are claims in advertisements restricted to unambiguous clinical outcomes or meaningful economic claims?
- If there are claims about surrogate endpoints is there also information that directly links changes in these end points to meaningful clinical outcomes?
- Are all claims for safety, effectiveness and cost-effectiveness in advertisements backed up by high-quality evidence (evidence from meta-analyses or randomised, controlled trials)?
- If there are claims for use of a medicine in a particular population are they based on high-quality evidence that comes from medicine use in that population?
- Is information about safety given the same prominence and placement as information about effectiveness?
- Do economic claims give actual prices of different alternatives? Are there vague claims about costs, such as “costs less”?
- Do advertisements for antibiotics recommend use that is consistent with guidelines to prevent unnecessary development of resistance?

Pictures and images in advertisements

Pictures and images in journal advertisements can help shape the way that doctors view patients. Some common portrayals are: as helpless victims of disease, as partners in developing therapeutic options, as people who are demanding, as being intelligent or emotional. The images in advertising can also sway how physicians and pharmacists view themselves, for example, as caring professionals able to solve a patient’s problem. These pictures can either reinforce or challenge generally held societal prejudices about different groups of people. Pictures and images can also serve as metaphors as advertisers seek to identify their products with a particular image, e.g., a maker of an antidepressant may hope to

The most common *Herpes simplex* Virus infection is Cold Sore, Fever Blister or Herpes Labialis or "Oral Herpes". It is an infection of the lips mostly caused by *Herpes simplex* Virus type one (HSV-1). An outbreak typically causes small blisters or sores on or around the mouth.

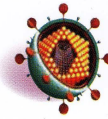
Cold Sores typically heal within 2-3 weeks, but the herpes virus remains dormant in the facial nerves, following orofacial infections, periodically reactivating to create sores in the same area of the mouth or face at the site of the original infection.

Aciclovir is a tested & trusted drug for the treatment of Cold Sore.

SQUARE offers

Virus®

200 & 400 mg Tablet
5% (50 mg/gm) Cream
200 mg/5 ml Suspension



Aciclovir BP

A relief from *Herpes Infections*

- ✿ **Effective in all types of herpes simplex infections**
- ✿ **Prevents the recurrences of genital herpes**
- ✿ **Ensures early recovery in chicken pox**
- ✿ **Effective in suppressing herpes zoster**
- ✿ **Safe in long term use**

Ref:rxlist.com



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Figure : A promotional brochure with Antiviral drug

identify its medicine with images of brightness as a symbol of recovery. The use of metaphors tends to reduce illness to a single dimension and treatment to a single modality (medicines) thereby taking illness out of its social context and simultaneously denying a role for any other form of therapy.

Box 4: How to evaluate pictures and images in pharmaceutical advertisements

- Do the people portrayed in the advertisements reflect the racial and ethnic composition of people in your country?
- Are both men and women portrayed in advertisements as both patients and health-care providers in equal numbers?
- Are the ways that men and women are portrayed (as workers, facial expressions, body language, etc.) similar?
- How are the elderly portrayed in advertisements?
- Are symbols or metaphors used in advertisements?
- What kinds of associations do these symbols and metaphors convey?
- Are illnesses portrayed as individual events or are they put into a social context?

CHAPTER 4

Data collection and Data Analysis

The brochures were collected from the selected company office. From the 98 brochure the following data was collected:

1. Number of promotional brochure found with combination of drug.
2. Number of promotional brochure found with Antibiotic related
3. Number of promotions brochure found with heart related
4. Number of promotions brochure found with Lung related
5. Number of promotions brochure found with liver related
6. Number of promotions brochure with different dosages form (tab, cap, drop etc)
7. Average number of reference taken from journals.
8. Average number of reference taken from websites.
9. Average number of references taken from books.
10. Numbers of promotional brochure found with no reference.
11. Numbers of promotional brochure found with 'TM' & 'R'.
12. Average amount of brochures found with more than one dose of a particular product
13. Whether the major side effects were included or not.
14. Whether the Placebo study in the brochures were included or not.
15. Whether the approved mechanism of action were present or not.
16. Whether the approved therapeutic uses were present or not.
17. Number of brochure found with no scientific evidence in favor of different claims..
18. Average number of brochures given pie chart to support a study.
19. Average number of brochures given bar diagram.
20. Average number of brochures given line diagram.

Results

1.Number of promotional brochure found with antibiotic related:

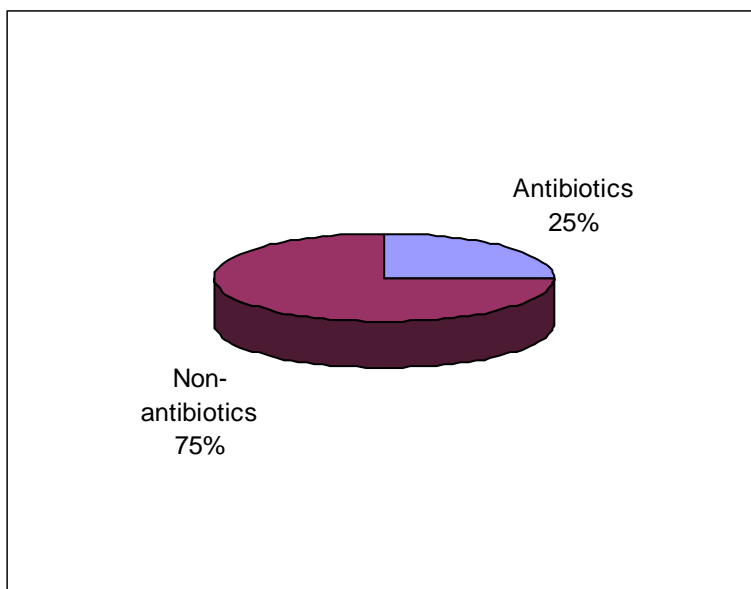


Fig: For Square Pharma

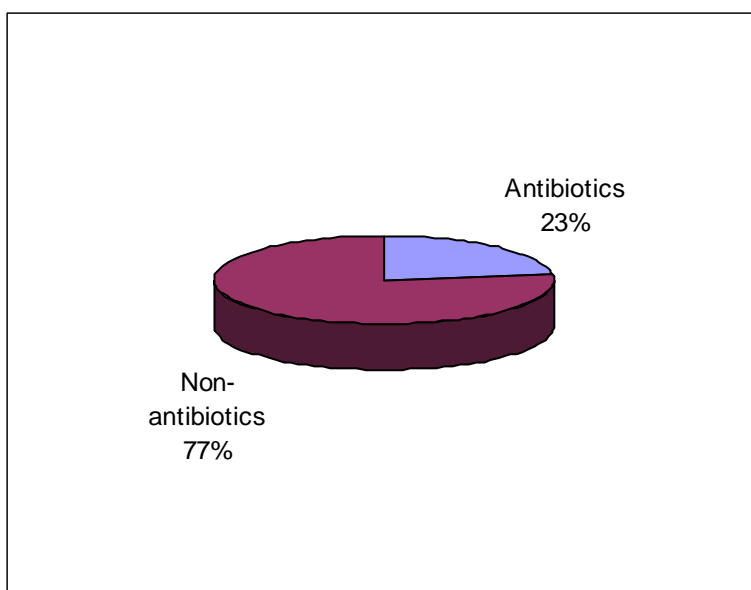


Fig: For Beximco Pharma

2. Number of promotional brochure found with 'TM' & 'R' related:

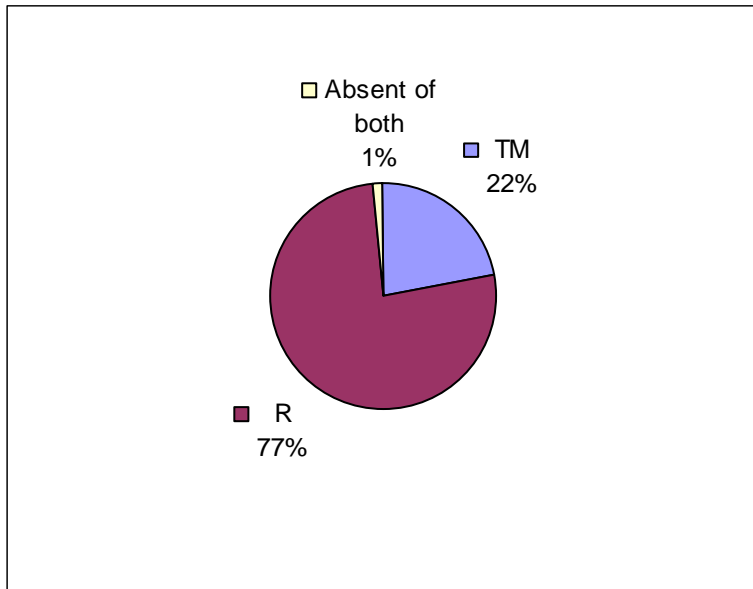


Fig: For Square Pharma

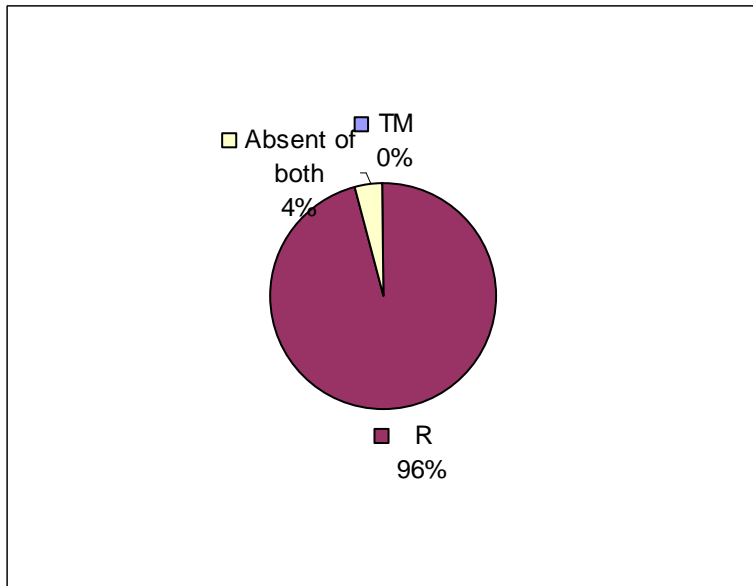


Fig: For Beximco Pharma

3. Number of promotional brochure found with combination of drug related:

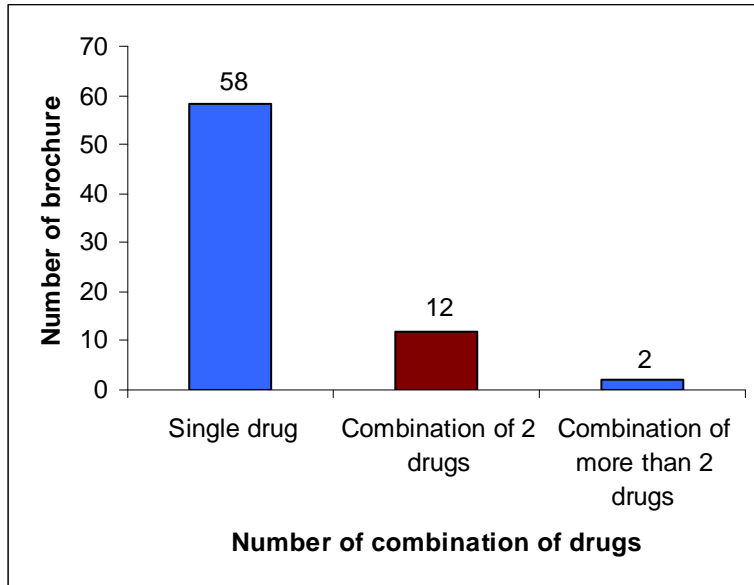


Fig: For Square Pharma

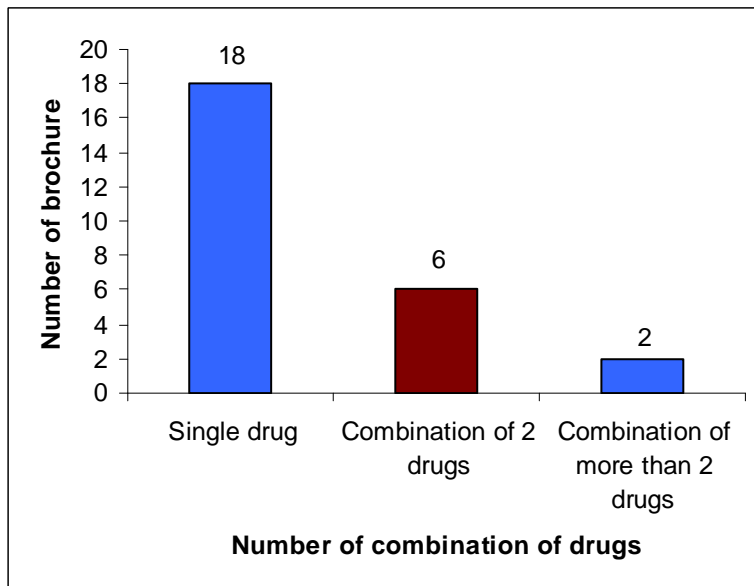


Fig: For Beximco Pharma

4. Number of promotional brochure found with diferent dosages form:

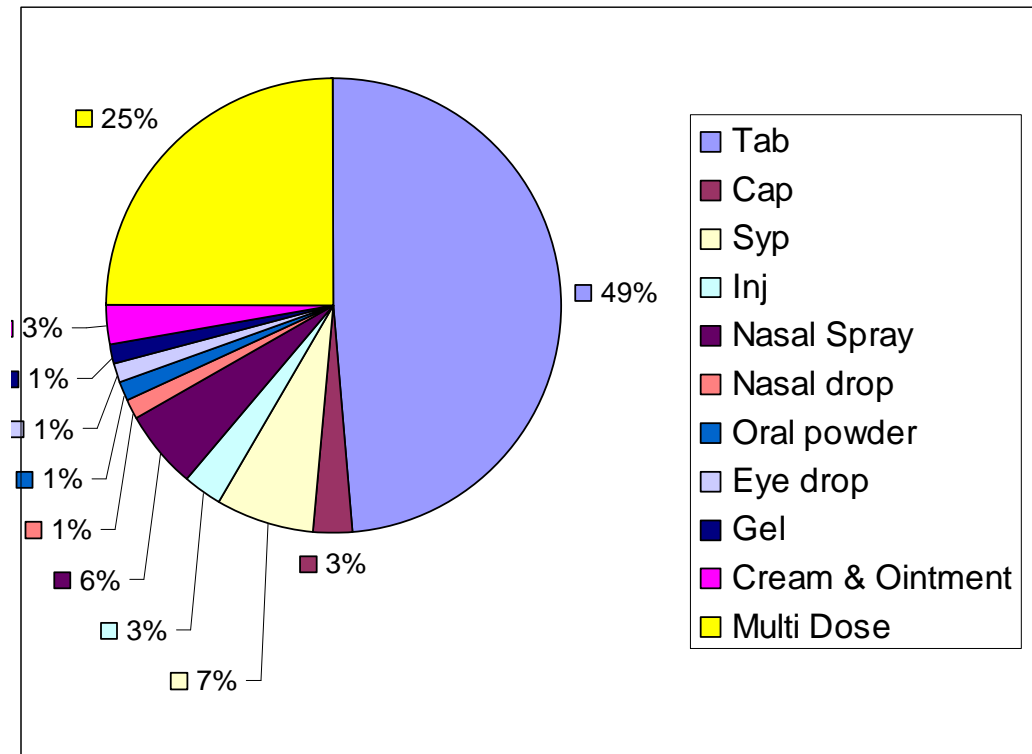


Fig: For Square Pharma

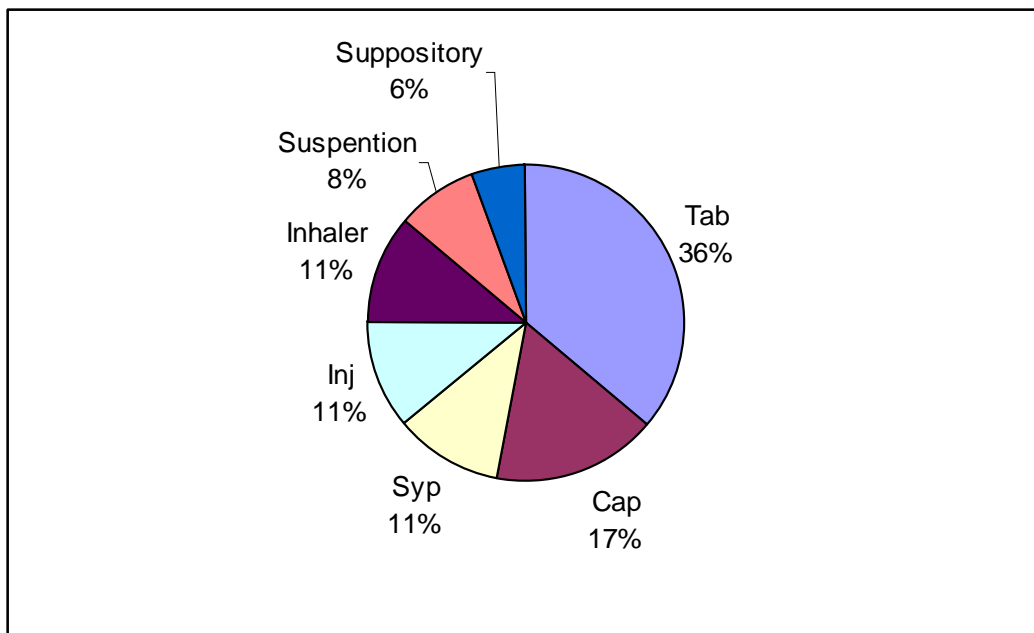


Fig: For Beximco Pharma

5. Number of promotional brochure found with diferent dosages form of tablet:

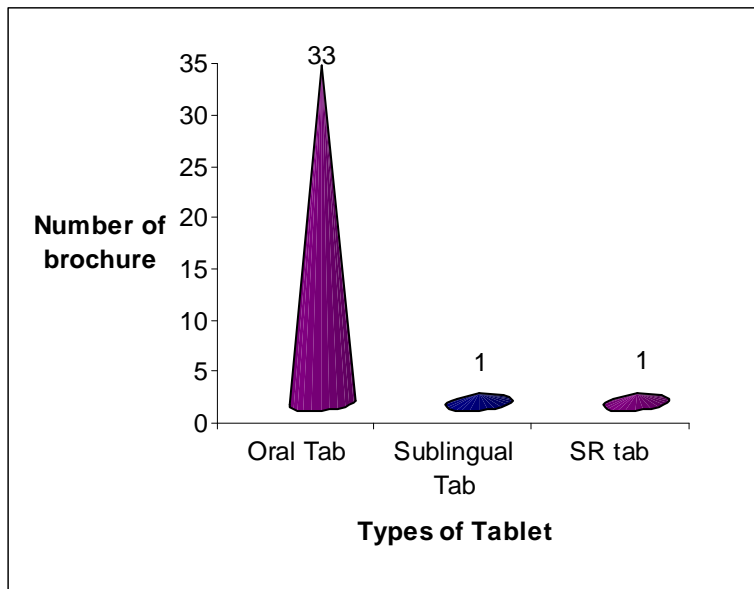


Fig: For Square Pharma

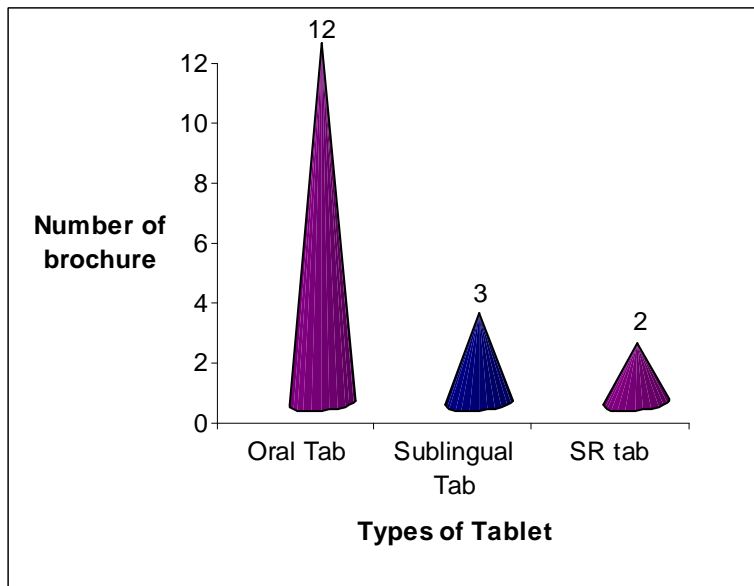


Fig: For Beximco Pharma

6. Number of promotional brochure found with diferent group of drug:

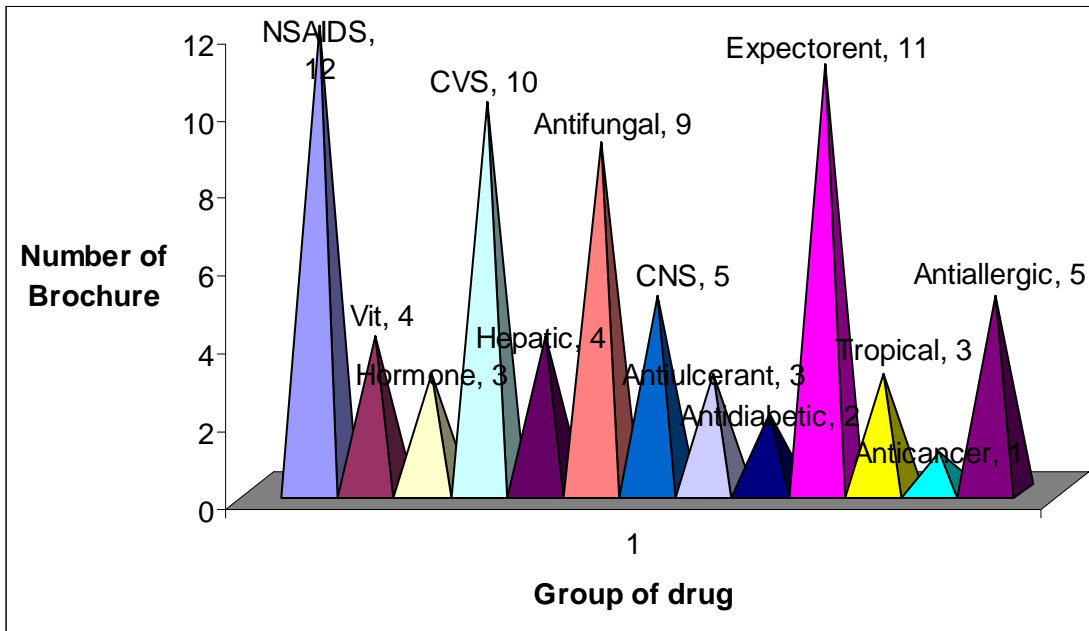


Fig: For Square Pharma

7. Different source of reference found in the brochure:

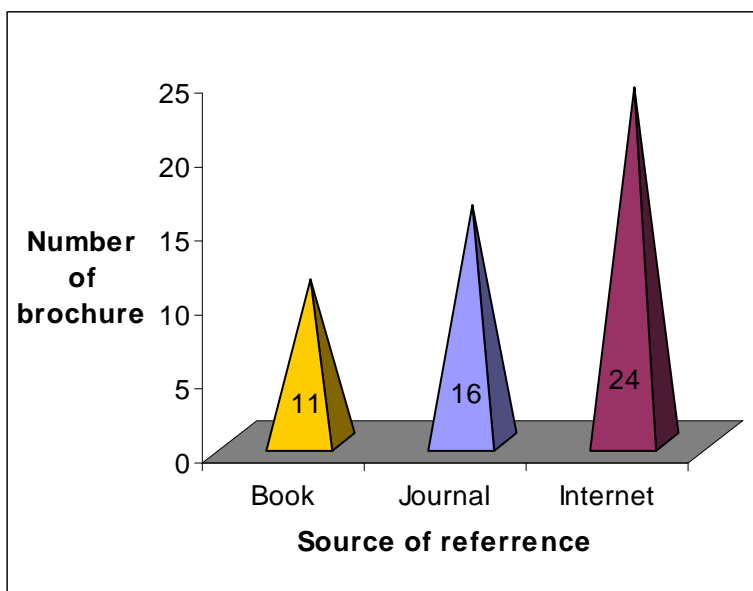


Fig: For Square Pharma

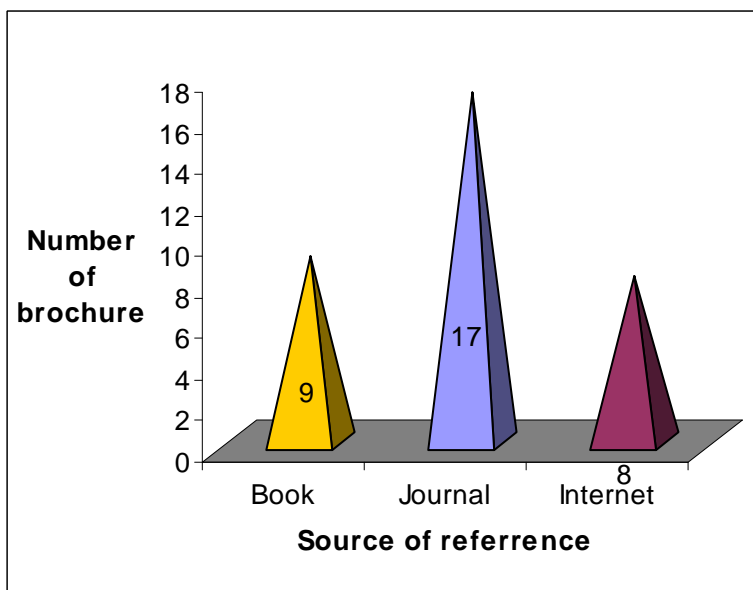


Fig: For Beximco Pharma

8. Number of promotional brochure found with no reference:

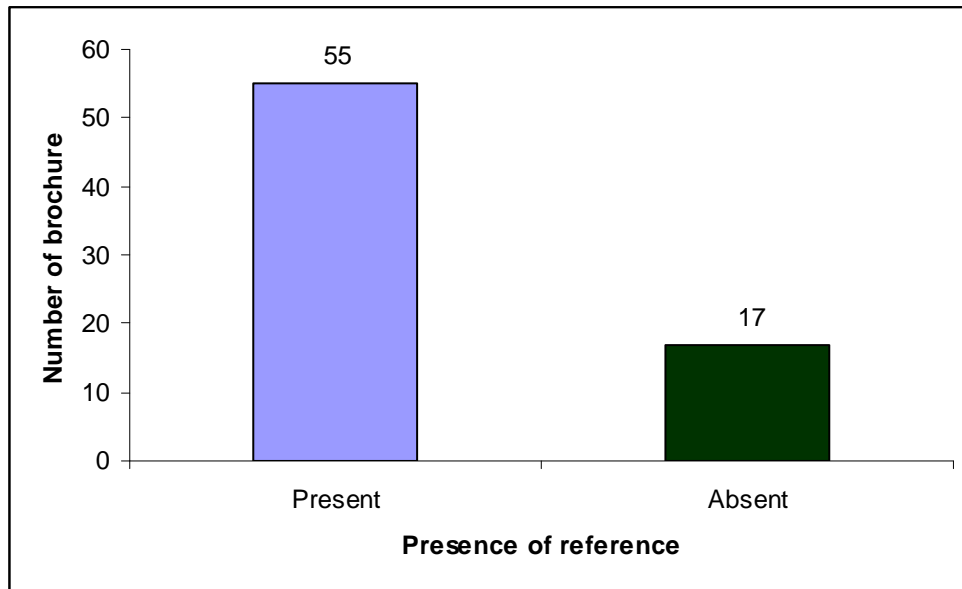


Fig: For Square Pharma

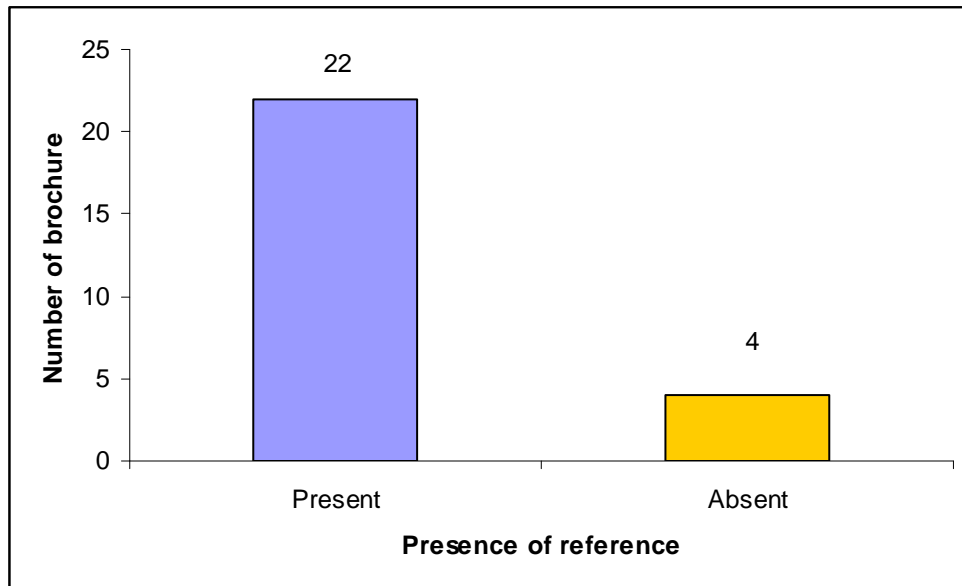


Fig: For Beximco Pharma

9. Number of promotional brochure found with major side effect:

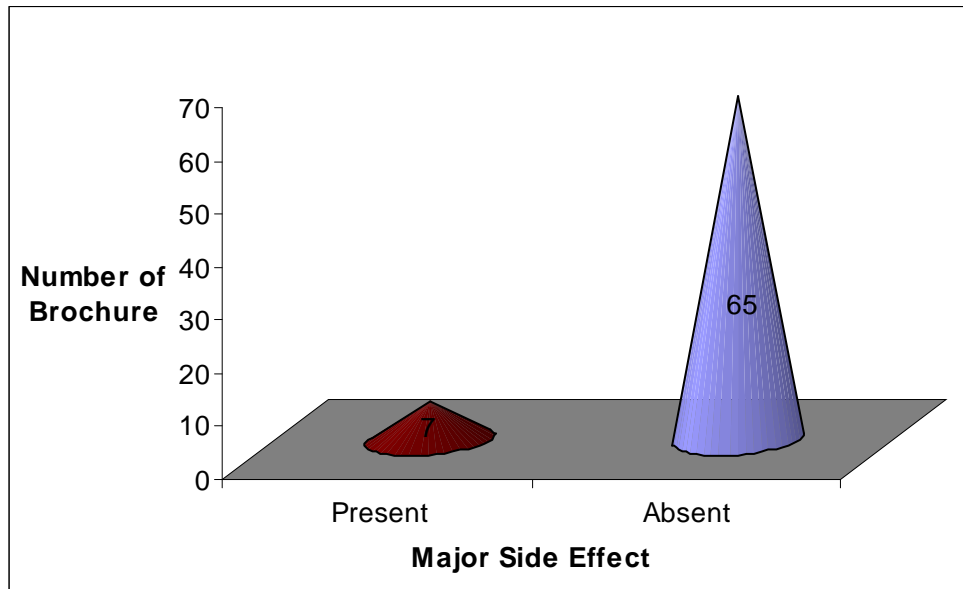


Fig: For Square Pharma

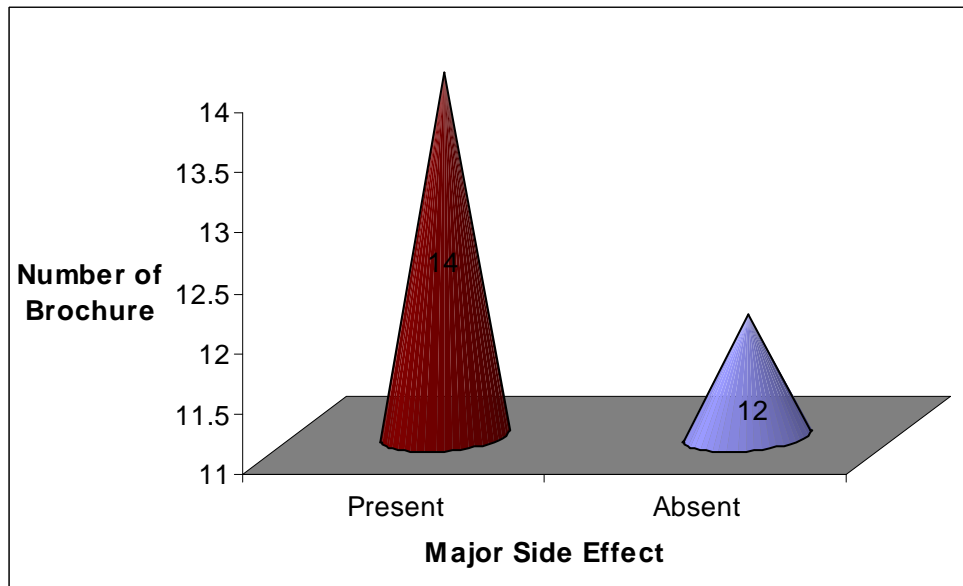


Fig: For Beximco Pharma

10. Number of promotional brochure found with placebo study or not:

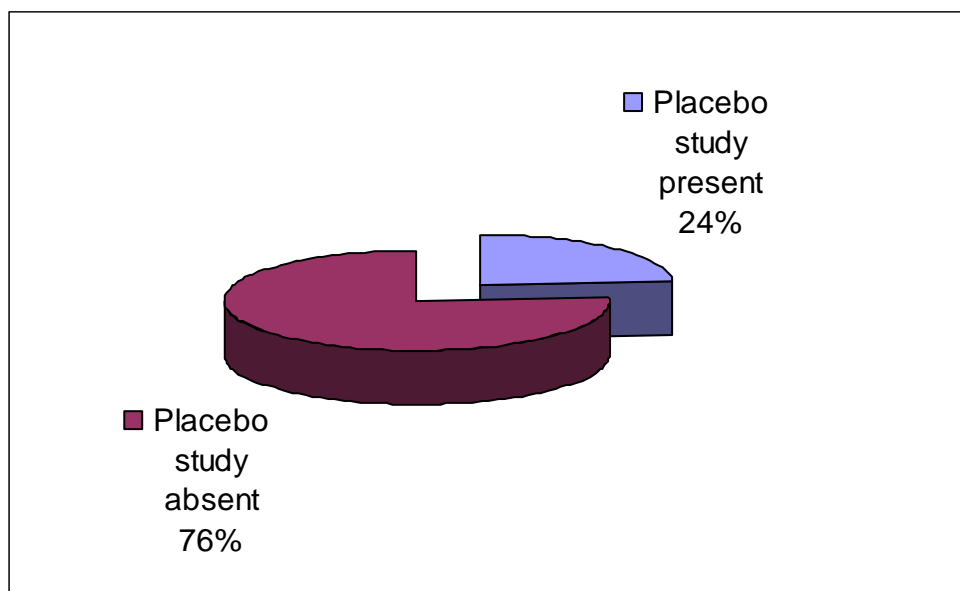


Fig: For Square Pharma

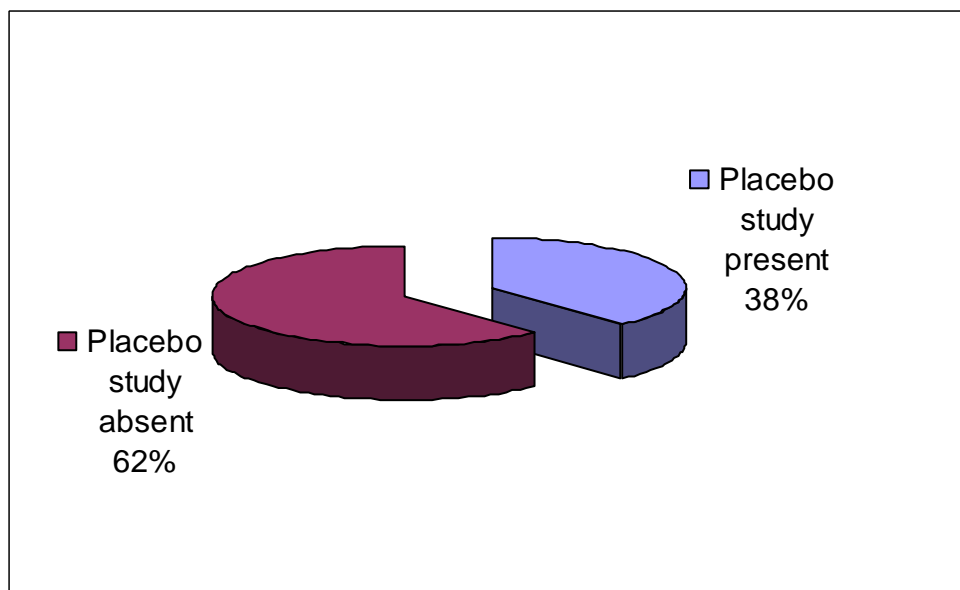


Fig: For Beximco Pharma

11. Number of promotional brochure found with M/A or not:

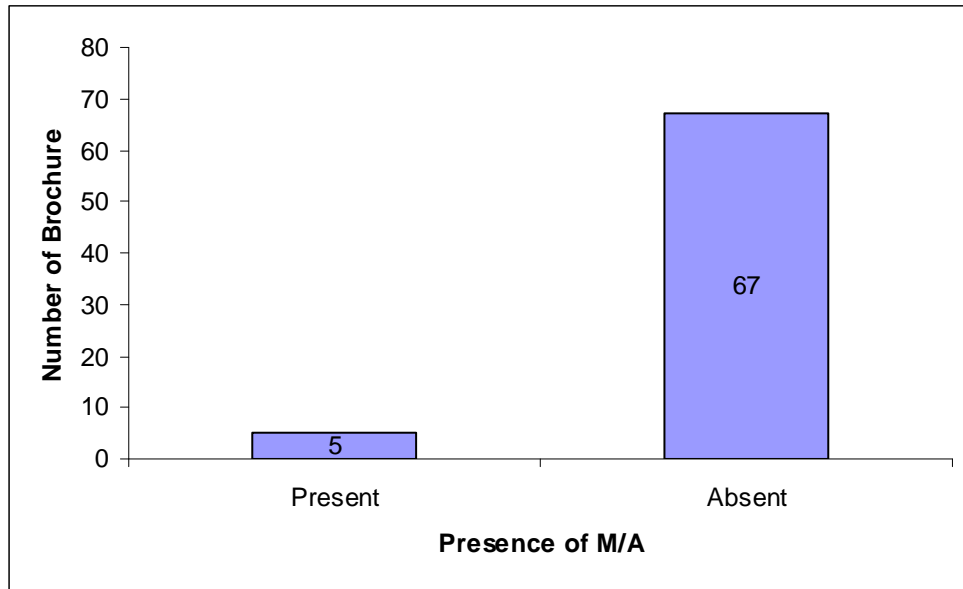


Fig: For Square Pharma

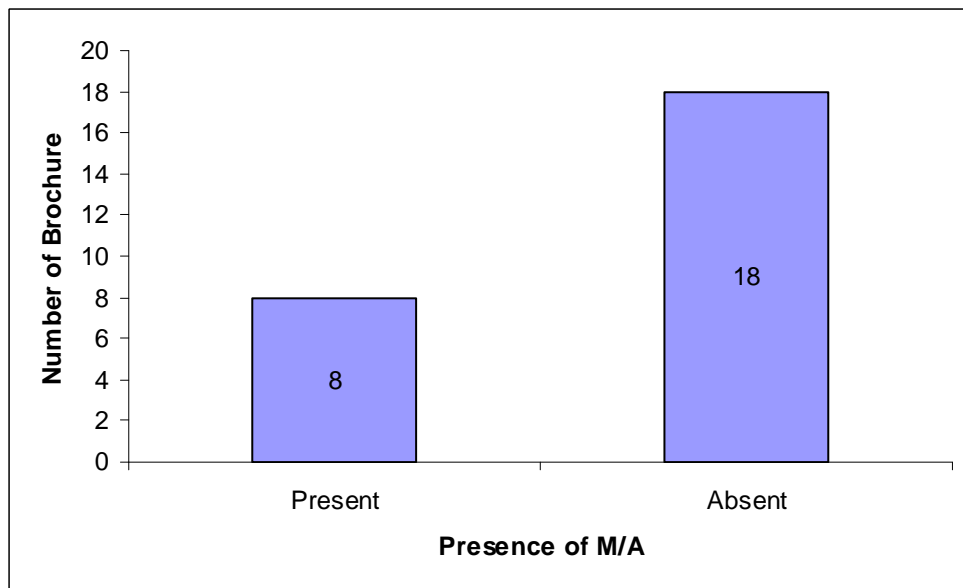


Fig: For Beximco Pharma

12. Number of promotional brochure found with secondary packaging materials:

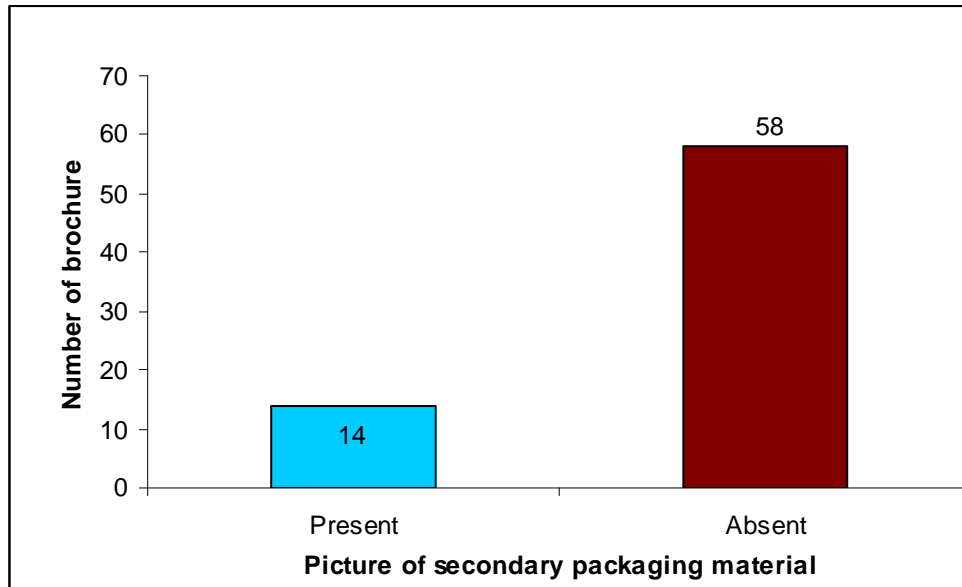


Fig: For Square Pharma

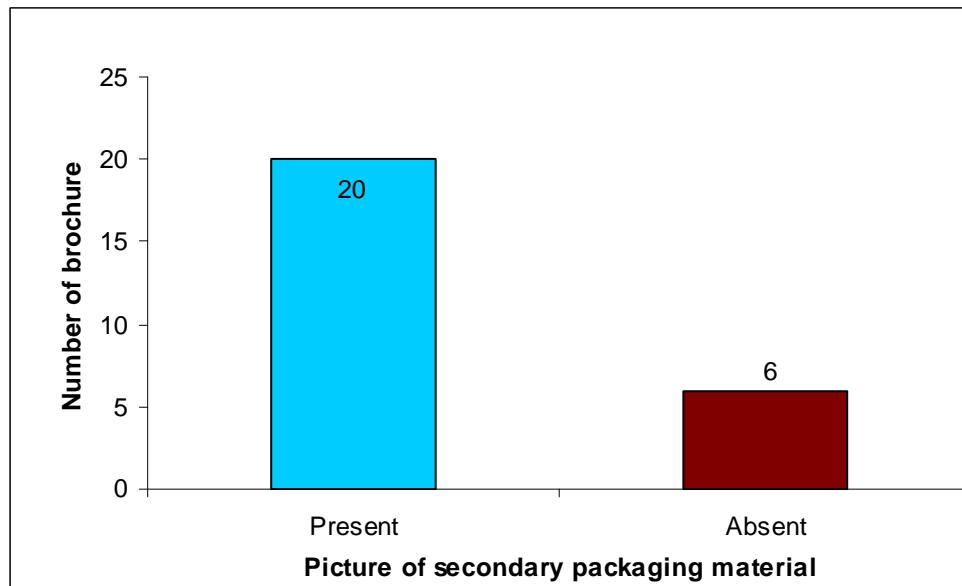


Fig: For Beximco Pharma

13. Grafical presentation(bar, pie, line etc) was present or absent in the brochure:

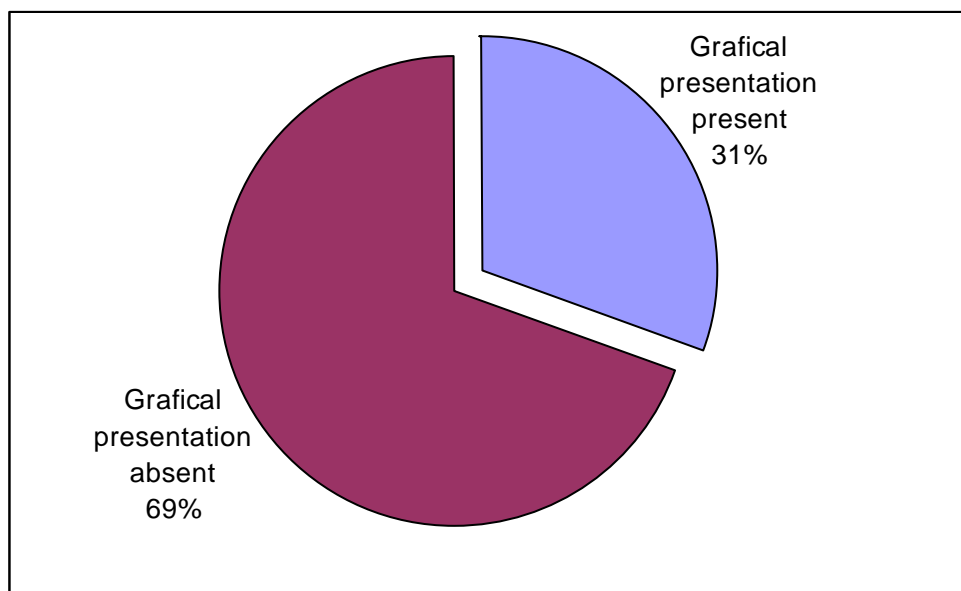


Fig: For Square Pharma

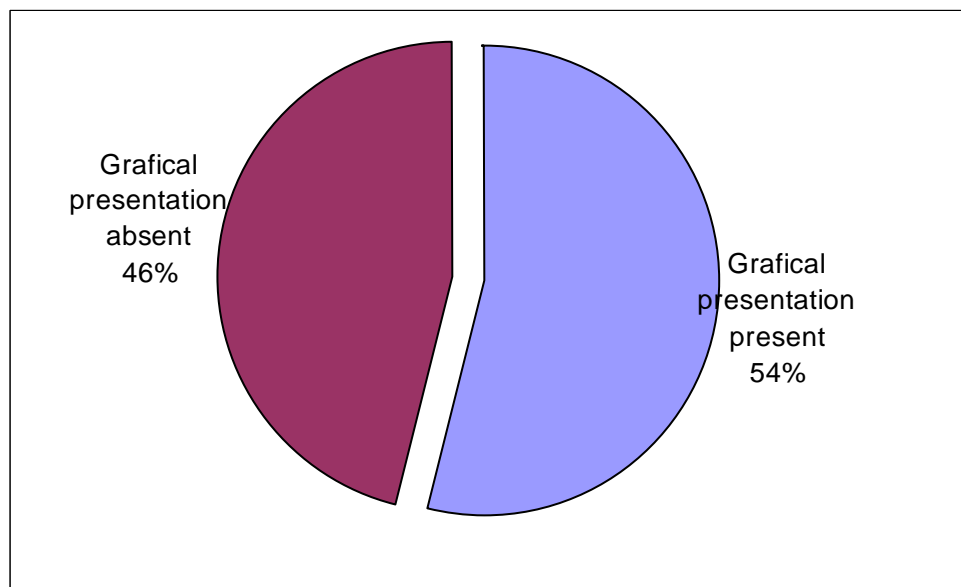


Fig: For Beximco Pharma

14. Percentage of presence of pie, line & bar diagram in the brochure:

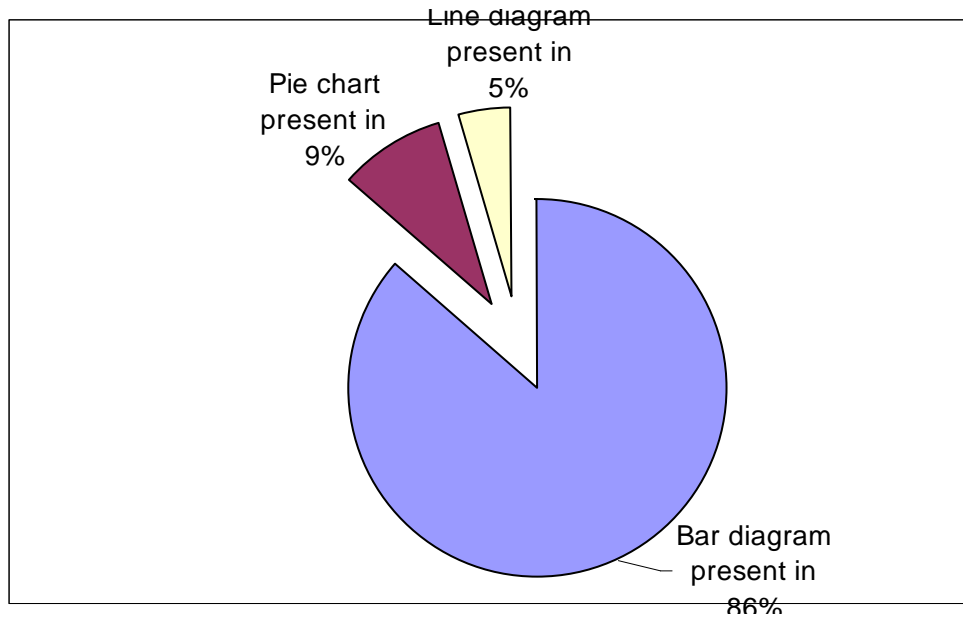


Fig: For Square Pharma

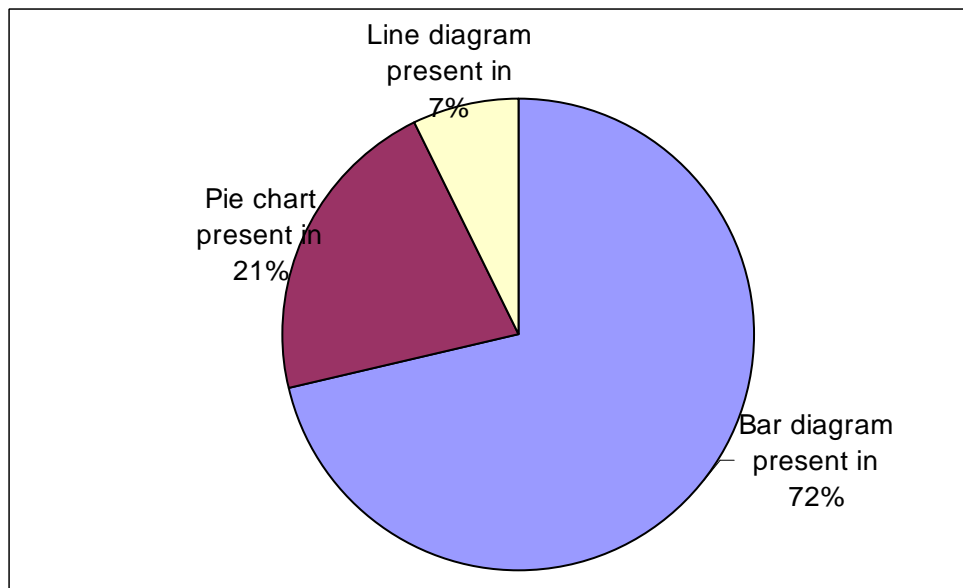


Fig: For Beximco Pharma

Discussion

The overall study is mainly based on critical evaluation of pharmaceutical information in drug promotional brochures. Drug promotional brochures are the most important sources of information about the drugs. As a result a majority of physicians are dependent on drug promotional brochures for information. As a result drug marketing has undoubtedly made an influence on their prescribing practices. The drug promotional practices carried out by the pharmaceutical industry would have undergone a huge change from the early days. Initially it began as a genuinely informative exercise to keep the doctors informed about the company's products. Now it has become more like a commercial relationship. For that assessment of the truthfulness of the drug promotional claims is very complex. But in this study the objectives of the information-based medicine was tried to analyze.

The study was conducted with 98 different promotional brochures. These promotional brochures were collected from Square Pharmaceutical Ltd & Beximco Pharma Ltd. Both are the leading pharmaceutical company.

The mostly promoted group of drug was antibiotic. Among the total promotional brochure of square, there was 25% antibiotic and 75% was nonantibiotic. This means that the use of antibiotic increase day by day. As antibiotic contain 25%, so it is amount of one fourth of total brochure. Among the total promotional brochure of Beximco, there was 23% antibiotic and 77% was nonantibiotic. This means that the use of antibiotic increase day by day. As antibiotic contain 23%, so it is amount of one fourth of total brochure.

This study also shows the presence of R and TM. R means registered and TM means Trade mark. In Square pharma, The number of promotional brochure found with R related was 77% and the number of promotional brochure found with TM related was 22%. But the number of promotional brochure found with no R and TM related was only 1%. That means most of the drugs are registered and few drugs are trade mark related. In Beximco pharma, The number of promotional brochure found with R related was 96% and the number of promotional brochure found with TM related was 0%. But the number of promotional brochure found with no R and TM related was only 4%. That means most of the drugs are registered.

This study shows the presence of brochure found with combination of drug related. In Square pharma, the number of promotional brochure found with single drug was 58 among 72. The number of promotional brochure found with combination of two drugs was 12 among 72. The

number of promotional brochure found with combination of more than two drugs was 2 among 72. So it is clear that the percentage of single drug is higher than the combined drug. In Beximco pharma, the number of promotional brochure found with single drug was 18 among 26. The number of promotional brochure found with combination of two drugs was 6 among 26. The number of promotional brochure found with combination of more than two drugs was 2 among 26. So it is clear that the percentage of single drug is higher than the combined drug.

In this study I try to show up the number of promotional brochure found with different dosages form. In Square pharma the pie data explain that, these promotional brochure contain different dosages form like tablet, capsule, syrup, injection, nasal spray, nasal drop, oral powder, eye drop, gel, cream & ointment. 49% of promotional brochure found with tablet related. 3% of capsule, 7% of syrup, 3% of injection, 6% of nasal spray, 1% of nasal drop, 1% of oral powder, 1% of eye drop, 1% of gel, 3% of cream & ointment, 25% of multidose related. So from this research it is clear that the dosages form of tablet is higher than the other dosages form. In Beximco Pharma, the pie data explain that, these promotional brochure contain different dosages form like tablet, capsule, syrup, injection, nasal spray, nasal drop, oral powder, eye drop, gel, cream & ointment. 36% of promotional brochure found with tablet related. 17% of capsule, 11% of syrup, 11% of injection. So from this research it is clear that the dosages form of tablet is higher than the other dosages form.

In this study I also try to show up the number of promotional brochure found with different dosages form of tablet. There are three types of dosages form of tablet was available in these brochure like oral tablet, sublingual tablet and sustain release tablet. In Square pharma, the oral dosages form of tablet was at highest amount 33. Each one brochure contain sublingual tablet and sustain release tablet. In Beximco pharma, the oral dosages form of tablet was at highest amount 12, sublingual tablet 3 and sustain release tablet are 2.

The number of promotional brochure found with different group of drug was also shown in this study. The total 72 brochure contain different group of drug like NSAIDS, vitamin, hormone, cardiovascular, hepatic, antifungal, CNS, antiulcerent, antidiabetic, expectorant, tropical, anticancer and antiallergic drug. The NSAIDS and expectorant group of drug contain highest number of brochure- 12 and 11 accordingly. Beside vitamin contain 4, hormone 3, CVS 10, hepatic 4, antifungal 9, CNS 5, antiulcerent 3, antidiabetic 2, tropical 3, anticancer 1 and antiallergic drug contain 5 brochure.

The analysis of different source of reference found in the brochure is also a part of my study. In Square pharma, most of the reference source of brochure obtain from internet which was 24. 11 & 16 brochures reference obtain from book and journal accordingly. In Beximco pharma, most of the reference source of brochure obtain from internet which was 8. 9 & 17 brochures reference obtain from book and journal accordingly. In this study I also found some brochure which had not take reference from book, journal or internet. In Square pharma, among 72 brochure reference was present in 55 and absent in 17. In Beximco pharma, among 26 brochure reference was present in 22 and absent in 4.

My study also shown up the number of promotional brochure found with major side effect. In Square pharma, among 72 brochure major side effect was present in 7 and absent in 65. So this is a great problem for brochure. In Beximco Pharma, among 26 brochure major side effect was present in 14 and absent in 12. So this is a great problem for brochure

My study also shown up the number of promotional brochure found with placebo study or not. In Square pharma, among 72 brochure placebo study was present in 24% and absent in 76%. So this is also a great problem for brochure. In Beximco pharma, among 26 brochure placebo study was present in 38% and absent in 62%. So this is also a great problem for brochure.

My study also shown up the number of promotional brochure found with mechanism of action or not. In Square pharma, among 72 brochure mechanism of action was present in 5 and absent in 67. So this is also a great problem for brochure. In Beximco pharma, among 26 brochure mechanism of action was present in 8 and absent in 18. So this is also a great problem for brochure.

The number of promotional brochure found with secondary packaging materials is also a important fector on my study. In Square pharma, among 72 brochure the picture of secondary packaging material was present in 14 and absent in 58. In Beximco pharma, among 26 brochure the picture of secondary packaging material was present in 20 and absent in 6.

The analysis of grafical presentation(bar, pie, line etc) was present or absent in the brochure is also a part of my study. In Square pharma, among 72 brochure the grafical presentation was present in 31% and absent in 69% of brochure. I also study the presence of pie, line & bar diagram in the brochure. The presence of bar diagram was 86% which was the highest. The

presence of line diagram was 5% and the presence of pie chart was 9%. In Beximco pharma, among 26 brochure the grafical presentation was present in 54% and absent in 46% of brochure. I also study the presence of pie, line & bar diagram in the brochure. The presence of bar diagram was 72% which was the highest. The presence of line diagram was 7% and the presence of pie chart was 21%.

Recommendation

Both the doctors and the manufacturers have an equal role to prevent the spread of such misleading information. There must be a monitoring authority to regulate the process. Although in Bangladesh there is a code of conduct but its application is very weak. Some recommendations for the manufacturer and doctors regarding the printed promotional material are given below:

Recommendation for Doctors

Doctors should maintain some guidelines while evaluating the literatures. The most important guidelines which should be followed by the doctors are given below:

1. The drug should be indicated for the conditions for which it is promoted as described by the existing guidelines. The disease under consideration should also be commonly encountered in the respective clinician's practice.

(McEvoy, Bethesda. 2007).

2. The physician should try to treat the patient with the existing recommended therapy and should check whether the new drug is better in overcoming the problems.

3. Careful attention should be paid to the drug with which the new drug is compared. The dose of the new drug should also be same as the comparator at which it is prescribed.

(Vusion, 2006)

Recommendation for Manufacturers

Manufacturers are mainly responsible for the misleading claims in the drug promotional brochure. Recommendations for manufactures related to drug promotional brochures are given below:

1. Transparent and verifiable information should be provided to the health professionals and pharmacists.

2. Codes of conduct on drug promotion should be extended to interactions with health professionals and consumers.

(Wood S, 2004).

3. The manufacturer should not influence any individual who is involved directly or indirectly in the writing, editing or publishing of the scientific information.

4. The information in the scientific or medical journal article or reference publications should not be false or misleading and should be derived ensuring adequate and well-controlled clinical investigations.

5. The information should not pose a significant risk to the public health. Scientific information should not be presented in a form that might bias the judgment of the physician and should be accompanied by the approved labeling of the drug. The scientific information should be distributed separately.

(Graham D, et al. 2005)

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