



Information content regarding regulation for advertising and promotion of pharmaceuticals in US, Europe, Australia and India

* Honey R Rathod, Dr. Dilip G Maheshwari

L.J. Institute of Pharmacy, Near Kataria Motors, Sanand Sarkhej Circle, S.G. Highway, Ahmadabad, Gujarat, India

Abstract

Now a day's Advertisement plays an important role in terms of promotion of any pharmaceutical product as well as influence the choice of consumer. Advertisement must be safe & efficient and should not be misleading and should promote health concern. Thus there must be strict regulations on advertisement. Regulations contain a frame work of advertising including the methods and format of advertising if not appropriate advertisement they have legal actions on it. Regulation in countries like US, Europe, Australia and India improves marketing and create awareness and provides guidelines and law to advertise pharmaceuticals.

Keywords: advertisement, regulations, framework

Introduction

Advertisement and Promotion

- Advertisement refers to the promotion and marketing of pharmaceutical products like medical devices, consumer diagnostics or drugs.
- Advertisement is an activity designed to influence individual choice.
- Generally it promotes prescription drugs and non prescription drugs.
- Prescription drugs are given on doctor's prescription for sever disease because of its specific use and risk and side effects.
- Non prescription drugs are used for general treatment.
- On the increase of their use they are referred as home remedies drugs or for self medication.
- The use of scientific information in advertising and promoting pharmaceuticals is commonly place the role of science in substantiating claims for regulators and clinical decision makers.
- The methods taught for making therapeutic decisions in advertisement are generally science and evidence-based.

Background

- Being the primary developers and producers of medicines the pharmaceutical industry plays an important role in public health care.
- It is highly dependent on marketing to expand product sales which may sometimes be unethical at the expense of the public health priority of rational use.
- It shows the impact for promotions of medicines on health professionals' behaviour, knowledge and attitude.
- It's evident that drug company promotions can change prescribing choices.
- Unethical promotion practices also affect ethics of company to grow local operations or to develop in cross-border trade.
- International regulatory standards for pharmaceutical

promotion exist in many countries, especially developing countries like US, Europe, Australia.

- In the pharmaceutical and advertising industries only self-regulation is implemented by the industrial associations.

Significance

- The regulation for promotion of medicines was identified as a critical priority in many countries in order to encourage rational use, ensure reasonable pricing of medicines and promote their growth.
- A system for pharmaceutical promotion which involves the society and the organisation in the monitoring of promotional activities will be significant.
- Specific guidelines are given that define ethical promotion and identify penalties for infringements may also be helpful in ensuring quality use of medicines by patients and at the same time helping the pharmaceutical industry sustain their operational quality.

Objectives

Regulatory models on pharmaceutical promotions in various countries that have clear and active involvement of civil society and other non-government stakeholders. Specifically it aims to:

- Present examples/cases of effective civil society-participated regulatory models for pharmaceutical promotions in other countries;
- Describes the current regulation process for pharmaceutical advertising in the country for the purpose of identifying its strengths, weaknesses and areas for improvement;
- Propose alternative regulatory models for pharmaceutical promotions involving community and organisation.
- Identify needs, resources and other requirements to support implementation and growth of proposed alternative regulatory models.
- It establishes creative strategy for providing guideline for

the company and the advertising agency on how to position the product in marketplace.

Role of Advertisement and Promotion

- Creating advertisements truly meant to educate consumers.
- Among the primary concerns surrounding DTCPA is the ethical outcome of largely-unregulated advertising.
- The advertisement should be responsible for assuring the safety of prescription drugs and retains discretion over their approval for a reason.
- Prescription medications are more potent carry a greater risk of misuse and have more specific indications as compared to over-the-counter drugs hence Prescription pharmaceuticals were originally intended to allow restricted access to those with specific conditions and in their need.
- The direct-to-consumer marketing has proven very beneficial for pharmaceutical companies; its observed that the prescription rates of drugs advertised directly to consumers “increased by 34.2%, compared to only 5.1% in other prescriptions”
- Introducing a new drug to market was not easy. Advertisement made it easy.
- Advertisement and promotion of pharmaceuticals encourages patients to educate themselves and understand what medications they are taking and why.

Functions of regulatory authorities

- Regulatory affairs also called government affairs. It is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, and banking.
- As function drug regulatory affairs regulates the pharmaceuticals science in order to trade in and outside the country within the origin of public interest.
- A good regulatory affair professional will play a very important part in coordinating scientific and endeavour with regulatory demands throughout the life of the product, will have first time approach and helping to maximize the cost effective use of the company’s resources.
- It plays important role for input in guidelines and guidance documents for uniform use.
- Gives marketing authorization application.

Regulatory Requirement for Advertising as per us

- Advertising and promotion is likewise within FDA’s jurisdiction. Control on advertisements is a collaborative work with the Federal Trade Commission (FTC), it ensures the correct presentation of benefit and risk information to patients.
- FDA ensures that advertisement should be genuine and not misleading. The FDA’s Division of Drug Marketing and Communication (DDMAC) controls the prescription drug advertising oversight to help assure that ads are in compliance with the FDA’s rules and regulations. It also monitors prescription drug promotion to physicians in many venues, including audio conferences, pamphlets distributed at professional meeting, mailings to health care professionals and all others.

- The Pharmaceutical Research and Manufacturers of America (PhRMA) is the IFPMA-recognized organization in the United States that sets appropriate standards with regards to pharmaceutical marketing and promotion.
- PhRMA Guides the Principles on Direct to Consumer Advertisement about Prescription Medicines and the Code of Interactions with Health Care Professionals.
- Companies must submit all television ads to the FDA before airing, so if an advertisement is in violation of the regulations, the FDA can prevent it from running to prevent any misleading information that can affect public safety.

Regulatory Requirement for Advertising as per Europe

- The European Federation of Pharmaceutical Industries and Associations (EFPIA), an IFPMA affiliated organization, represents the pharmaceutical industry operating in Europe.
- IFPMA’s mission of promoting high standards in marketing and promotion, the EFPIA codes were created namely – Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (the “HCP Code”) and Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations (the “PO Code”).
- In the United Kingdom, advertising of medicines is acceptable provided that it is in line with legislation and agreed standards of good practice. In general, advertising any commodity and services to the public must be of high standards and it should not cause serious or widespread offence, create unrealistic expectations in the consumer or be misleading.
- The MHRA will only act when there is a clear case for protection or if self-regulation fails. (MHRA the Blue Guide, 2014)

Regulatory Requirement for Advertising as per Australia

- Pharmaceutical promotion and advertising in Australia is governed by the Therapeutic Goods Act of 1989 (The “TG” Act), the Therapeutic Goods Regulations of 1990 (“The TG Regulations”) and the Therapeutic Goods Advertising Code (2007). Promotion is also subject to the requirements of the Trade Practices Act (1974).
- Advertising therapeutic goods is also subject to other laws that regulate advertisements such as the Competition and Consumer Act of 2010 and the Australian Consumer Law, both of which ensure consumer protection and safety.
- The advertising of therapeutic goods to consumers and health professionals is administered via a co-regulatory system which is representative of all key stakeholders – consumers, health professionals, the regulated industry sectors, the media, advertisers and the government.
- This is regulated by both co-regulatory and self-regulatory arrangements operated by the TGA under the Act and Regulations, the Therapeutic Goods Advertising Code Council 5 (TGACC).
- Prior approval is required for advertisements and generic information of non-prescription medicines in various forms of media

Regulatory Requirement for Advertising in India

- Pharmaceutical advertisement and promotion comes under drug and magic remedy act.
- The Indian advertising market is fully regulated and controlled by a non statutory body, the ADVERTISING STANDARDS COUNCIL OF INDIA.
- Advertisement should be done after the approval or under observation of government agencies, its aims to cure certain disease and serve to the public.
- The government agencies should identify and promotes health campaigns regarding drug information services.
- There is a strong need to observed and verify the range, availability, clarity and particularly the quality of independent and unbiased information regarding prescription drug on advertisement or on mass media.

Framework

A frame work is the body of advertising including the methods and format of advertising

The framework has the complaints section for the non-appropriates advertisements and have legal actions on it. There are certain claims on endorsements thus provision is important.

It also provides Promotion of services on internet sites with entire descriptions for it like disease awareness and health education and also provides material for patients.

Press releases other information to the media. Responses to enquiries from the public, Vetting of advertising material, Scrutiny of current advertising material and gives Corrective statements on misleading advertisement and Seeks advice on advertising

Initially it is important for preapproval process of the advertisement; it passes through various approval processes by different departments.

Thus any claim in the advertisement should be made clear and then should be published.

Conclusion

Here in countries like USA, Europe, Australia has very stringent regulations for advertisement and promotion where in India there are very few regulations regarding advertisement hence to reduce the chances of fault advertisement the regulation must be followed strictly.

Acknowledgement

The authors are thankful to Dr. K. Pundarikakshadu, Director of L. J. Institute of Pharmacy; Ahemdabad, India for providing all the facilities and encouragement to carry out the work and also thankful to Dr. Jignesh S. Shah for providing support and knowledge.

Reference

1. Grant A. The role of advertising in pharmaceuticals, MDG advertising, 2011. <https://www.mdrnyu.org/spring-2016-the-role-of-advertising-in-pharmaceuticals/>
2. Danzong M, Furukawa MF. Pharma the facts about pharmaceutical marketing and promotion, 2004.
3. FDA and the Internet: Advertising and Promotion of Medical Products – Presentations. <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm175793.htm>
4. Blue guide: advertising and promoting medicines. <https://www.gov.uk/government/publications/blue-guide-advertising-and-promoting-medicines>
5. Advertising the therapeutic goods. <https://www.tga.gov.au/advertising-therapeutic-goods>
6. Pharmaceutical direct-to-consumer advertising in Europe. <https://www.pharmafield.co.uk/features/2005/12/Pharmaceutical-direct-to-consumer-advertising-in-Europe#>
7. Guidance for Industry Consumer-Directed Broadcast Advertisements. <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm070065.pdf>

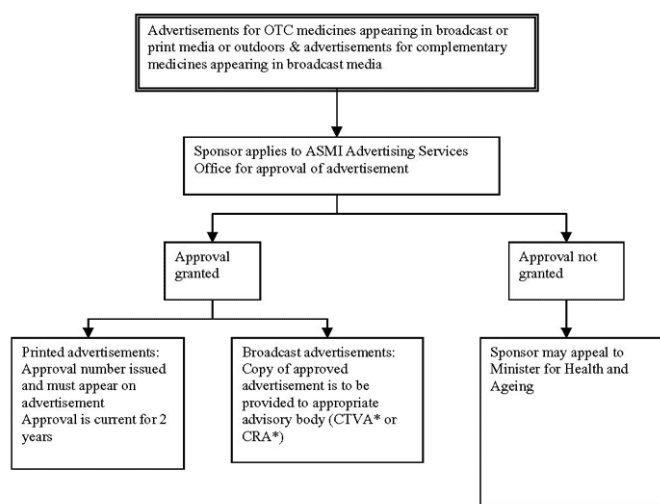


Fig 3: Describes the approval process of advertisement.

A claim says something about the advertised drug or what it does. Claims usually relate to benefits. Claims can be made directly by stating, for example, "Brand X treats heartburn." Claims also can be made indirectly by the use of pictures or other graphics.