Research Paper Pharma

Dealing with Unethical Drug Promotion Practices in India

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ABSTRACT

The Streptococcal M protein was found to be on the receptors of Streptococci cells. They are the important protein that acts as a barrier for the phagocyte activity of the host cell. The M-protein resists the ingestion and killing of the host immune system because of its virulent receptors. In this study the M-protein are extracted from the Streptococcus pyogenes and subjected to purification. The purified form of the protein is used to raise the immune response in mice model.

Keywords : Pathogen, M-protein, Microsphere, Affinity, Virulent factors, Receptors

Introduction

Medicines can play a crucial role in the attainment or maintenance of health but it is vital that they are used rationally. If a patient needs treatment, he or she must have access to the right medication, in the right dosage and for the appropriate course of treatment. Health-care professionals such as doctors and pharmacists, play a key role in ensuring that medicines are used appropriately. As gatekeepers to care, they need to assess different treatment options, including pharmacotherapy, and consider each for potential benefit and harm. In 1994, the World Health Organization (WHO) published the Guide to Good Prescribing. This publication was developed and field tested extensively before its release. After publication, it was translated into multiple languages and was widely used. This guide highlighted the need for students to learn to focus in a very practical way on treatment goals when making prescribing decisions, and to develop their own personal formulary for commonly treated conditions. The report of the evaluation was published in The Lancet (1995).

However, in recent years, growing concern has focused attention on the relationship between health-care professionals and the pharmaceutical industry - particularly the industry's influence on prescribing and dispensing decisions through a range of promotional tools, which can influence treatment choices. This influence can lead to less than optimal medication choices, sometimes to the detriment of patient health. Despite the fundamental nature of these treatment decisions and the important role of pharmaceutical promotion in shaping them, health-care professionals receive little or no instruction on how to assess pharmaceutical promotion and how to understand its often subtle influence on their behavior. In 2005 a WHO/Health Action International (HAI) cross-sectional, international survey of educational initiatives on pharmaceutical promotion found that whilst many medical and pharmacy faculties included this topic in their curriculum, most spent less than one day on the subject - with some schools devoting only one to two hours to the issue. The survey also showed that even though educators recognize the need for instruction on pharmaceutical promotion and sometimes do their best to incorporate it into their work, it is mostly limited.

The pharmaceutical industry is an important source of health care for billions of population globally and in India. Hence it is a highly regulated sector. The pharmaceutical industry is influenced by a host of practices which may primarily relate to price regulations, insurance and reimbursements, drug procurement by government agencies, patent laws, innovation polices, biotechnology and safety policies, drug regulation, data protection, trademarks and use of international nonproprietary names, drug promotion regulation, drug advertising regulation etc... Hence competition law has to work in tandem with all such diverse set of laws, polices and regulation governing the pharmaceutical sector.

When we take the 'routine' headache pill or a prescription medicine, little do we realize that there is a complex web of processes related to pharmaceutical production, distribution and marketing; diagnostic and therapeutic procedures and standards; global trends; as well as policy formulation, implementation and oversight related to government departments as diverse as health, chemicals, industry, labor, law, finance and others, that influence our decisions. It is well known that for the 'patient' the consumption of a medicine, unless it is a result of self medication, is not a matter of 'choice', but is determined both by the science of 'medicine' and by 'market forces' that define the relationship between the doctor and the medical representative (MR).The relationship among pharma industry, physicians and public policy is not only complex, but often irrational, unethical, and' unscientific'. In times when accountability and transparency are becoming increasingly common ideas, it is important to unravel these relationships and introduce these complexities in scientific and public discourse. This is important because the Indian drug companies are often seen as the 'David' of the global pharmaceutical industry,'saviours' for millions who can now access affordable anti-retrovirals, and leading the economic charge from an industrial 'underdog' country in the era of globalised trade. At the same time the cost of healthcare, mostly that of medicines, continues to be a leading cause of impoverishment and indebtedness in India.

Pharmaceutical promotion

The pharmaceutical industries (PI) throughout the World are heavily involved in aggressive drug promotions, with a clear aim to change the prescribing habits of physicians and to encourage the self-medication of patients. Broadly, drug promotion refers to all the informational and persuasive activities of the PI, the effect of which is to induce prescription, supply, purchase, and use of medicinal drugs. It includes the activities of medical representatives, drug advertisements to physicians, provision of gifts and samples, drug package inserts, direct-to-consumer advertisements, periodicals, telemarketing, holding of conferences, symposium and scientific meetings, sponsoring of medical education and conduct of promotional trials. The PI has the right to promote its products, but it should do so in a fair, accurate, and ethical manner. The promotional claims need to be reliable, truthful, informative,

balanced, up-to-date, and capable of substantiation in good taste. However, now a days, whilst the promotional methods have become very sophisticated and effective, it was found that while promoting their products, the PI does not adhere to these ethical principles. Hence, in most situations, these lead to irrational use of drugs. This unfortunate situation could be tackled only by the multiple prong strategy involving government, PI, doctors, medical associations and consumers. The government is required to formulate some guidelines in addition to developing their own code. The doctors and consumers are required to be educated on the promotional practices and abuses committed by the PI and different ways to tackle those. Various medical and consumer groups should also intervene to improve the scenario of promotion.

Pharmaceutical promotion influences the prescribing behaviour of health professionals. The pharmaceutical industry differs from other industries in that its products directly affect the health of patients. The pharmaceutical promotion is double edged: it is necessary to effectively market a product; but can also harm the interests of consumers. This is especially so with medicines. Unethical promotion practices of the pharmaceutical industry have caused grave harm to the public and the society.

Three Cs of Promotion

The three Cs of promotion generally adopted by the pharmaceutical industry all over are convince, confuse and corrupt. Medicine is a commodity where the consumers have no choice. It is the sole responsibility of prescribers to select the medicine or rather the brand of medicine for their patients thus making industry's job easier to simply convince the prescriber. A number of strategies adopted in promotion to convince a prescriber may not act, and then comes the need to confuse the prescriber in some other way. In case both these process do not yield results, the easy way to achieve success is to corrupt the prescriber.

The term promotion explicitly involves profit as the role of information and dissemination of knowledge. Promotion itself is aimed to generate demand which may or may not preexist. It may be debatable issue whether a medicine is required to be promoted even if it is essential; yet promotion has become a very integrated term with medicines. One can argue that medicines are part of business not charity, and therefore profit is also a key motive for the pharmaceutical industry. Brand promotion with inflated claims for other commodities can be acceptable with some limitations. Brand promotion for medicines is acceptable provided that the drug industry adheres to a framework of ethics. In the absence of ethics, regulation or application of sparsely available law, this industry can do enormous harm as is evident from a closer look at our country.

Medical Representatives

Every pharmaceutical company employs and trains medical representatives to promote and sell drugs, using printed product literatures, drug samples and gifts. In India, an estimated 1,00,000 representatives are employed by the industry. Besides the salaries, they also receive incentives for achievement of sales targets, which might tilt the balance in favour of aggressive drug promotion. While doctors uniformly deny that their understanding of drug is influenced by the activities of industry, there is considerable evidence to support the efficacy of the personal encounter with a medical representative in shaping doctors' attitude towards drugs. In a UK survey of general practitioners, 58% mentioned a sales representative as the source of new products they prescribed. The doctors surveyed also felt that sometimes the information on side-effects was not enough and more indications were promoted than registered. There are no such systematic studies in India. However, any practicing physician can see such examples.

Gifts

One of the tools used by pharmaceutical industry is to give gifts to the doctor. The variety of gifts include stationery, time related, bags, books, folders, office/desk, medical, household, personal and innovative items. The list includes small and big - alarm clocks to air-conditioners, calendars to cars, rubber bands to refrigerators, telephone index to television and office items to overseas trips. Although this apparently innocuous practice is generally accepted as a norm many doctors feel about its ethical repercussions.

Whenever a physician accepts a gift, an implicit relationship is established between the doctor and the company or its representatives and there is an obligation to respond to the gift. The gift usually reminds the doctor about the brand-name of the drug and results in a prescription. However, gifts cost money which is ultimately passed on to the patients without their explicit knowledge. American College of Physicians advises that a gift should not be accepted by the doctor, if acceptance might influence the objectivity of clinical judgment.

Certain educational gifts e.g. books, journals or case record forms and trivial gifts such as pens and calendars may be considered acceptable. The ABPI code advices companies to distribute gifts which are inexpensive and relevant to practice of medicine. The American Medical Association and US Pharmaceutical Manufacturers Association guidelines suggest that the gifts should involve a benefit for the patients and should not be of a substantial value and should not be accepted if there are "strings" attached for prescriptions. There is a need for a discussion between the professional medical associations and the industry to define acceptable norms for gifts.

Gifts of different values would then be given to the doctors after counting the prescriptions they have generated. Thus this kind of crude inducement is openly and generously practiced by the pharmaceutical industry in India. Here we can perceive that how the best students sent for medical education in our country are entrapped by the industry. Doctors often do not keep track of what they are prescribing; for whom they are prescribing and what their commitment to society is. The bond between the industry and the profession has become so profound that ethics is sacrificed.

Advertising

Advertising is an art of arresting one's intelligence long enough to make money out of it. Doctors interact with the pharmaceutical industry in various ways. Most common are direct face-to-face visits from company representatives. The more a drug is promoted either through pharmaceutical sales representatives or journal advertisements, the more it may influence physician's prescribing habits. As the major source of information to a majority of doctors and pharmacists, MRs have a role in helping practitioners to know about the drugs available in the market and their costs. It is the practitioner's duty to use MRs while taking care not to be unduly influenced by their sales pitch.

No medical journal in India can survive without the advertisements of a drug. The pharmaceutical industry spends heavily on advertising in journals with a wide circulation meant for a clinical specialist or general practitioners. But in India, the basic journals e.g. clinical pharmacology, pathology find it difficult to manage, because of lack of advertisements. Besides the advertisement, the many western journals also carry full text of approved information on a drug. This practice could help the journal in generating additional revenue and also help the reader in getting balanced information on a drug. The advertisements and printed promotional material such as visual aids used by the medical representatives, banners and posters at conferences and exhibition stalls and direct mailings to doctors usually include rational-product / therapy / clinical use related and emotional - humour / curiosity / ego-gratifying appeals. A good balance between these two appeals would make the information educative and interesting. Often the marketing interests tilt the balance in favour of emotional aspects.

However, today advertising of a drug is under close scrutiny. A sample study of advertising in leading medical journals in 18 countries found that important warnings and precautions were

missing in half the 6700 advertisements surveyed. Some of the Indian companies have even started drug advertisements in lay press. When captopril was introduced, one local company started an information service, which was advertised in national newspapers. Some companies put drug advertisements "for attention of medical profession" in newspapers. Under the disguise of reaching doctors, they are trying to influence the patients. With availability of drugs without prescriptions, the patient can buy a new drug and suffer its undesirable consequences. Although it is mandatory in most countries to provide a printed package information (for doctors and patients) on a drug in every drug pack, many companies do not provide this information in India,

Currently, several measures to improve the quality of advertising and promotional information are being undertaken. The IFPMA code (International Federation of Pharmaceutical Manufacturers Associations) and ABPI codes suggest that the drug information should be accurate, current and balanced. Superlatives must not be used and word 'safe' should not be used without qualification. The product or services of other companies should not be disparaged either directly or by implication. Quotations from medical literatures must accurately reflect the meaning of the author and the significance of the study and complete reference should be given. All promotional material must include a succinct statement about the indications, contraindications, precautions, side-effects and dosage. Besides it should conform to canons of good taste. All member companies of Organization of Pharmaceutical Producers of India (OPPI) have to follow IFPMA code. Many OPPI members have their own internal codes and the promotional material has to be approved by the medical advisor. There is also a Promotional Quality Improvement and Assurance Committee to critically analyse the promotional material, which has already gone to doctors and to suggest improvements in subsequent marketing communications. However, in many companies in India, there are no qualified medical advisors and in many, marketing department takes overriding decisions on promotional materials, particularly if the medical staff reports to the marketing manager.

Hospitality for medical profession and seminars

Conventional methods of drug promotion have increasingly been supplemented by non-traditional approaches such as symposia that rely heavily on the involvement of medical researchers and other experts. Over the past two decades, the number and cost of such events have increased dramatically. In India, there are hardly any meetings, seminars or conferences held without funding from the pharmaceutical companies. The pharmaceutical industry may well be considered a primary source of continuing medical education; but, these activities are often promotional and they can undermine the unbiased exchange of scientific information and raise questions of professional ethics. Many such activities that are arranged through the marketing department of a company rather than its medical or research department tend to jeopardize the scientific legitimacy and objectivity.

Besides organising such events, the industry also supports travel and hospitality for the speakers and even audience! It is also unfortunate that Indian medical personnel have begun to approach the drug firms for assistance in their intention to attend the conferences in India and abroad and threatening the representatives of drug firms with non-cooperation or boycott the products of firms if they don't comply".

These activities have been criticized and guidelines proposed for the conduct of medical meetings. The sponsor of an activity should not have express or implied control over the scientific content of the programme. The meetings should be organised through a recognised medical association and the seminar should focus on treatment of a disease or a therapeutic class. In India, OPPI supports medical education activities of several medical associations without any involvement in the content or the organisation of the seminar. The discussion must be balanced covering a range of views and the data presented must be reliable. Anecdotal or personal use of a drug is not acceptable. The post-seminar activities such as journal supplements on a product are also to follow above guidelines. Physicians are advised to avoid involving themselves with programmes that emphasize recreational events. In India, there is an urgent need for the industry and the medical associations to develop responsible guidelines.

Rational use of medicines

In many developing countries, pharmaceutical companies have been accused of exploiting the lack of independent information available to medical professionals and patients. In the absence of independent sources doctors, the public and patients have to rely to a much greater extent on companies' marketing to tell them about the products that are available.22 When the information that is provided is misleading, biased and inaccurate it contributes to dangerous levels of mis-prescribing. Up to 50% of medicines in developing countries are inappropriately prescribed, dispensed or sold. The problem is compounded when drug companies also release misleading messages and information to the public and patients. It is also estimated that 50% of patients in developing countries improperly use medicines.24 Such high levels of irrational use are likely to be having a disastrous impact on people's health resulting in reduced treatment efficacy and contributing to problems like drug resistance.

Consequences and future scenario

Although the doctors have the sole and absolute power to determine the sales of drugs, which are available on prescriptions, the pharmaceutical marketing and promotion practices are blamed for irrational prescribing habits and their consequences. In a study of large number of prescriptions, it was found that the nutritional supplements were advised in 53.4%, antibiotics in 31.2% and analgesics in 26.2%. In a study of anti-inflammatory drug usage, we found that ibuprofen and combinations were used by over 60% of patients and the use of aspirin - a poor man's drug - was quite low. There was no difference in the drug usage in different rheumatic diseases. Indomethacin or phenylbutazone are more effective in seronegative arthritis; however, their usage in these disorders was low. There are many examples of misuse of potent drugs like antibiotics, digoxin, steroids etc. The consequences of such inappropriate drug use are unnecessary adverse effects, increase in antibiotic resistant microorganisms, treatment failures from use of wrong drugs and the waste of the patient's money.

There is a need both for the industry and doctor to develop mutually agreeable limits for promotion of drugs. The available codes provided a useful guideline; but they are still considered the beginning rather than the end of this debate. With the medical profession coming under the ambit of consumer protection act, it is likely that industry - doctor relationship might come under such scrutiny. In France, under a government law, physicians who accept any form of payment from drug companies can be fined FF 500,000, jailed for two years and struck off the recognition for ten years.

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 [WHO 2006].

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. International bodies, the pharmaceutical industry and various other national professional or industrial

organizations have voluntarily been developing and implementing codes of practice for the promotion of medicines. These have generally been based on the Ethical Criteria for Medicinal Drug Promotion, published by the World Health Organization in 1988. The WHO Ethical Criteria and the codes of practice provided by international pharmaceutical organizations are often used as examples in the design of a national code of practice.

In order to improve the rational use of medicines, promotional material must be fair, accurate and not misleading. The consistency of promotional material with available product information and the substantiation with scientific evidence are critical to assuring the quality and accuracy of drug promotion. The distribution of promotional material should be restricted in order to prevent an inaccurate image of certain drugs by 'overwhelming promotional activities'. Therefore, the presentation, substantiation and distribution of promotional material are described in self regulatory codes on pharmaceutical promotion in order to maintain high standards.

Improving Environment for Inventing and Patenting New Chemical Entities

With the transformation of the international trade regimes, the Government of India is increasingly active in assisting Indian companies with export, new drug discovery and clinical research. [Department of Chemicals and Petrochemicals]. . The Government has introduced tax relief on research and development expenditures, loans on easy terms for drug discovery, and schemes to encourage collaborations between companies and public sector institutions. In the run-up to the 2009 national elections, the Department of Chemicals and Petrochemicals announced eye-catching proposals to raise up to $2 billion annually through tax-free bonds to promote drug discovery and innovation-based pharmaceuticals industry in the country, in order to gain up to 20 percent of the world's R&D business. Critics of these plans suggest that inadequate attention has been paid to the conditions in which drug discovery and testing is currently regulated. Specialists in medical ethics have accused some drug companies carrying out clinical trials in India of 'compromising science and ethics in the pursuit of profit' and that inadequacies in the oversight mechanisms allow clinical trials to recruit the 'desperate' and 'most vulnerable' members of Indian society. Ensuring that these latter concerns are addressed is a task well beyond the competence

Establishing a Centralized National Drug Authority

Under the Constitution of India, the regulation of 'Drugs' is a concurrent subject, so the responsibility is divided between the Central Government and the State and Union Territories Governments. Unlike the movements to decentralise aspects of governance in India, since at least the 1970s the central Governments has tried to reduce states' autonomy and centralise control in this field. The Hathi Committee of 1975 first proposed a national pharmaceuticals agency, to provide uniform standards and a single authority to register drugs, to ensure uniform standards across the country.

Although the 1978 National Drug Policy made no mention of this, the 1986 and 1994 Drug Policies proposed National Drug Authorities to monitor drug quality according to standard procedures. The 1999 Mashelkar Committee proposed establishing a Monitoring Authority to oversee Good Manufacturing, Good Laboratory and Good Clinical Practice – but this, too, was not implemented. The 2003 Mashelkar Committee proposed to strengthen the existing Central Drugs Standard Control Organisation (CDSCO) and the State Drug Controllers and create a Central Drug Authority (CDA) – a line also followed in the 2002 Drug Policy. Apparently, 15 state governments supported this idea. Nonetheless, in 2005 the Pronab Sen Committee returned to a centralising proposal, to 'integrate the offices of the Drugs Controller General of India, the Central Drugs Standard Control Organisation (CDSCO) and the National Pharmaceutical Pricing Authority (NPPA), along with all the powers and functions of these bodies' A Bill was introduced in Parliament to establish a CDA, and Mashelkar's views on this were regarded as so significant by the Parliamentary panel charged with investigating the Bill that it delayed its report until he had been consulted. The draft Bill was heavily criticised by the committee and the need for redrafting led to its being abandoned before the Lok Sabha elections of 2009.

Despite these repeated proposals, by 2009 the Government of India had made little progress towards creating a National Drug Authority, perhaps partly because, health being constitutionally on the concurrent list, centralisation of drug control may pose additional legal hurdles.

Local-language labelling and information sheets

Most patients in India are not literate in the English that is used in drug information packs. Add to this that – as in many other countries – drug information varies from brand to brand, leading to the possibility of misleading patients and prescribers about appropriate use, co-occurring effects and drug interactions. A WHO study called for "further training and continued education aimed at drug regulatory officials" to "provide the necessary knowledge and enable national authorities to meet the need for drug information that is independent of commercial interests" but no substantive moves have been made in this direction in India.

Conclusions & Recommendations

Governments

Key recommendations:

1. Implement, improve and monitor legislation in line with the WHO Resolution on the Rational Use of Medicines and the WHO Ethical Criteria for Medicinal Drug Promotion.
2. Support the provision of independent information on drugs for consumers and health professionals.
3. Implement and enforce a ban on gifts to doctors.
4. Enforce strict sanctions that will deter poor corporate practice in drug promotion.
5. Take measures to improve the transparency of drug companies' marketing activities and seriously address the conflict of interest encountered in drug companies' funding of medical education.

At the 60th World Health Assembly held between 14 and19 May 2007, member governments agreed an important new resolution on the rational use of medicines. The resolution included a call on all member governments: "to enact new, or enforce existing, legislation to ban inaccurate, misleading or unethical promotion of medicines, to monitor drug promotion, and to develop and implement programmes that will provide independent, non-promotional information on medicines." This resolution is a clear signal to all countries of the importance of this issue and the action that needs to be taken.

Ensuring high standards in the promotion of medicines is important to consumers' health and helps to save money for health providers and patients. Without proper controls consumers can be subject to misleading or inaccurate claims and the promotion of expensive branded medicines that have no greater medical value than cheaper non-branded products. Whilst the pharmaceutical industry clearly has an important role to play in tackling the health challenges their involvement in the promotion of medicines presents a serious conflict of interest.

It is equally important that health professionals have access to independent and up to date advice on medicines so that they can make informed judgements about the most appropriate medication for patients.

Governments must make continued medical education (CME) a priority and alleviate the need for doctors to rely on industry-dominated information provision mechanisms.

Improved regulation of drug promotion will generate a number of benefits for various stakeholders. Consumers will have a

better chance of getting the most appropriate drug for their condition. Regulations that lead to improved drug use can lower direct costs (e.g.subsidy costs and import costs) which should be welcomed by governments and tax payers. Finally, socially responsible drug companies will also benefit if regulation helps to create a level playing field and prevent unscrupulous companies from manipulating the market through irresponsible marketing.

The pharmaceutical industry
Key recommendations at the company level:

1. Stop the practice of gifts to doctors
2. Implement rigorous policies on vetting of drug promotion materials and adherence to existing codes of conduct
3. Provide transparent and verifiable information on the precise nature of relationships and associated funding for all stakeholder groups, including health professionals, pharmacists, students, journalists, clinical research organisations and patient groups.

At an industry-wide level:

1. Ensure codes of conduct on drug promotion extend to interactions with health professionals and consumers.
2. Invest in innovative partnerships with government and civil society organisations so that corporate funding of disease awareness campaigns, and CME may be channelled via blind trusts in line with specific health priorities of consumers at a community or national level.

According to IFPMA, "promotional activities must be consistent with high ethical standards and information should be designed to help health care providers improve services to patients. Information must be provided with objectivity, truthfulness and in good taste and must conform to all relevant laws and regulations. Claims for therapeutic indications and conditions of use must be based on valid scientific evidence and include clear statements with respect to side effects, contraindications, and precautions." It also stresses that "high standards of ethical behaviour shall apply equally to marketing of pharmaceutical products in all countries, regardless of the level of development of their economic and health care systems."

The IFPMA Secretariat continues to handle complaints of alleged violations of the IFPMA Code of Pharmaceutical Marketing Practices. IFPMA supports self-regulation as the most appropriate mechanism for regulating marketing and promotional practices by companies." In doing so, IFPMA often refers complaints on to national industry bodies. The codes of national bodies, particularly in the case of developing countries, are often weak and IFPMA'S referral system can result in the lowest standard being applied to serious ethical breaches.

Fundamental and systemic changes are required to ensure that the promotion activities of companies respect consumer rights to safe and reliable products and to independently verifiable information about the safety and efficacy of those products.