Blurring the Boundaries: Introduction

Barbara Mintzes | 1998 | Download PDF

Citation: Mintzes, B. 1998, Blurring the boundaries: new trends in drug promotion, Health Action International, Amsterdam

In a keynote address to an international conference on management in Paris in 1997, Kurt Briner, Chief Executive of Sanofi Pharma, rejected the idea of any conflict of interest in communication between the pharmaceutical industry and consumers. He dismissed this suggestion as, "an insult to our industry, an insult to our ethics as healthcare professionals and an expression of utter contempt for the numerous legal obligations by which we are bound by our ethical practice."[(1)]

The pharmaceutical sector is highly profitable and companies depend on expanding product sales in order to maintain their competitive edge. The proportion of total sales revenues allocated to marketing has been rising continually.[(2)] A 1997 article by Devlin and Hemsley in *Scrip Magazine* estimated that pharmaceutical companies spend approximately 35% of sales revenues on marketing[(3)], around double the proportion spent on research and development.

As shown by many of the examples in this report, the ethical dilemma of competing marketing and health interests is real and not simply an insult to the industry as Briner claims. The underlying problem is a tension between optimal use of medicines only if and when they are known to improve health, and the pressure companies are under to continuously expand product sales. The World Health Organization (WHO) described "an inherent conflict of interest between the legitimate business goals of manufacturers and the social, medical and economic needs of providers and the public to select and use drugs in the most rational way."[(4)]

There is an enormous imbalance in the financial resources available to produce commercial, promotional information on drugs as opposed to the limited resources available for comparative, independent information and assessments. For example, in the UK, which does a much better job of providing independent drug information to doctors and pharmacists than most countries, the ratio of spending on drug promotion versus publicly-funded independent drug information was estimated to be 50 to 1 in 1997.[(5)]

Although this paper addresses new trends in drug promotion, many of the underlying concerns will be familiar to health workers, consumers and industry analysts. Are misleading messages, unsubstantiated claims, and unbalanced information a problem of the past? In a 1992 article on promotion in the US, Louis Morris and J. Griffin of the US Food and Drug Administration (FDA) strongly disagreed: "From FDA's perspective, companies have dramatically increased the sheer level of questionable promotional practices."[(6)] They pointed both to an increase in the quantity of promotional activities in response to

increasing competitive pressures and to new sophisticated promotional techniques which bypass current regulatory controls.

Increasingly, promotional messages are aimed at the public as well as health professionals. In the US, unlike other industrialized countries, direct-to-consumer (DTC) promotion of prescription drugs is allowed. As reflected in the meeting at which Dr Briner spoke, other regulatory agencies are considering whether or not to follow the US model. At stake here is whether consumer health or commercial interests are to be given priority. The question is not whether consumers should obtain information about treatment options; the question is whether drug promotion–whose aim is to sell a product–can provide the type of information consumers need. Philip Brown, an industry analyst, says in an editorial on promotion to consumers in *Scrip Magazine* that: "It is not that companies are not to be trusted to tell the truth, rather I believe that they should not be put into a situation where the question even arises."[(7)]

WHO defines drug promotion as: "all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs."[(8)] By definition the aim of promotion is to stimulate product sales.

How should promotion be regulated if the guiding principle is the best possible use of medicines, only if and when they are needed, in the interest of individual and public health?

In a recent meeting on control of drug promotion on the Internet sponsored by the US FDA, Dr Juhana Heikkila, Director of WHO's Division of Drug Management and Policies, explained that two-thirds of the world's countries either have no laws to regulate pharmaceutical promotion or do not enforce the regulations they have.[(9)] Studies of doctors' prescribing in industrialized countries show that inappropriate prescribing, likely to lead to poorer health outcomes, is more frequent among doctors who rely more heavily on promotional information sources.[(10)] In other words, even in the remaining one-third of countries with better drug regulation, the messages in promotional materials lead to poorer prescribing.

An international standard

If national regulatory controls are inadequate can international guidelines ensure adequate standards for regulation of drug promotion? As one element in the implementation of its 1985 Revised Drug Strategy, WHO developed a set of *Ethical Criteria for Medicinal Drug Promotion.* These criteria were adopted by the 1988 World Health Assembly and were the result of a consensus discussion involving health workers, drug regulatory agencies, consumers and the industry.

The WHO *Ethical Criteria* state that promotion of prescription and over-the-counter drugs:

- should be consistent with national health policies
- should contain reliable claims, without misleading or unverifiable statements
- should contain no omissions which could lead to health risks

- should not be designed so as to disguise its real nature, for example as educational or scientific activities.

The *Ethical Criteria* also include general guidelines for advertisements to the medical profession and the public, conduct of sales representatives, free samples, symposia and scientific meetings, post-marketing studies, packaging and labeling, patient information and promotion of exported drugs.

Although some areas of drug promotion are inadequately covered by the *Ethical Criteria*, their guiding principle, to "support and encourage the improvement of health care through the rational use of drugs", remains a universally applicable standard. However, the *Ethical Criteria* are neither well-known nor well-used by regulators, health professionals, industry staff or the public. Joe Collier of the *Drugs & Therapeutics Bulletin* and Robin Fox of *The Lancet,* commented that*:* "Sad to say, these clear and straightforward criteria have been much neglected."[(11)]

Collier and Fox were reporting on a meeting hosted by WHO and the Council for International Organizations of Medical Science (CIOMS) to explore ways to implement the *Ethical Criteria*. The meeting recommendations included monitoring, developing performance indicators, remedial measures if promotion is inadequately controlled, periodical review of the Criteria, a framework for national capacity building, and development and dissemination of educational materials on the *Ethical Criteria*. These recommendations remain valid today. Preliminary results of a multi-country study on the implementation of the *Ethical Criteria* reported in 1996 indicated, "very little awareness of the *Ethical Criteria*, national regulations or industry codes among doctors, pharmacists, health workers or industry sales representatives, as well as inadequate government regulation of all aspects of promotion, but especially sales representatives, symposia and post-marketing studies, weak monitoring, and a lack of sanctions.[(12)]

The other operating international standard is the International Federation of Pharmaceutical Manufacturers' Association (IFPMA) Code of Pharmaceutical Marketing Practices developed in 1981 and revised in 1994. It describes itself as defining "universally applicable baseline standards of marketing practice."[(13)] However, this voluntary industry self-regulatory code lacks any mechanisms for active monitoring, effective sanctions, or clear procedures to correct misleading information. Without enforcement, it remains "more show than substance," as Andrew Herxheimer, author of several studies of industry self-regulation, has commented. "The spirit of the code is usually disregarded…The same companies repeat their transgressions again and again."[(14)]

Although the IFPMA code states that it is a minimum global standard for drug promotion, both the 1981 and 1994 versions also allow for precedence of national laws and regulations: "In all matters of application, interpretation and enforcement…compliance with national laws, regulations and regulatory decisions and requirements will take precedence."[(15)] This can be a problem if national regulation is weak and drug uses have been approved without the scientific evidence to back them. The Medical Lobby for Appropriate Marketing (MaLAM), an international network of health professionals, questioned Organon in 1992

about their marketing of adrenochrome for “prevention and treatment of surgical and non-surgical capillary bleeding” in Bangladesh. Dr Vemer, Organon’s Medical Director, sidestepped the problem of lack of scientific evidence because Bangladeshi health authorities had endorsed this use, stating that: “according to our interpretation of the IFPMA Code of Pharmaceutical Marketing Practices a company which has a pharmaceutical product evaluated and registered by an established regulatory authority can be considered as having provided adequate scientific evidence.”[(16)] This defense remains permissible under the 1994 IFPMA code, in effect preventing the code from providing even a minimum standard for drug promotion where national regulations are weak.[(17)]

National drug regulatory agencies are responsible for approval and licensing of drugs which are marketed within their country as well as other regulatory decisions, including approval of the information which accompanies drugs and governs their use. Multinational companies market their drugs in many countries and must therefore make many separate applications for marketing licenses for each product. At the same time, national drug regulatory agencies are often swamped with drug applications. The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was set up in 1989 by European, Japanese and US regulatory agencies and the international research-based industry in order to harmonize this process and develop mutually recognized registration procedures for drugs.

Could international harmonization of drug regulation ensure better control of promotion? In theory, yes, if health were to become a central focus, but thus far the ICH has paid far more attention to rapid international registration. This is reflected in the emphasis of the press statement released after the second major ICH conference, “ICH is developing consensus on a series of guidelines which will permit more rapid international registration of new drugs and biologicals whilst continuing regulatory obligations to protect public health.”[(18)]

Rapid registration of new drugs will not necessarily lead to better health outcomes. Catherine Hodgkin of Health Action International (HAI-Europe) points out that: “Of the 47 new chemical entities approved in the world in 1994, only two were thought to be important therapeutic advances over existing therapy.”[(19)] Promotion has not been highlighted as a priority for international harmonization. One of the problems is who has been left out of the decision-making process and priority-setting for international harmonization of drug regulation: consumers, health professionals, regulators from developing countries and transitional economies, domestic industry from these regions and generic manufacturers. It is no wonder that rapid registration of new drugs is taking precedence over a broader public health perspective.

A global trend towards trade liberalization and encouragement of open markets, together with inadequate national regulatory controls, has led some countries to quickly register many new pharmaceutical products. For example, in 1994 Poland registered 334 new drugs, an average of almost one a day. Dr Chrusciel, Chair of Pharmacotherapy for the Polish Physicians’ Chamber, judged that about 40 of these drugs improved the range of therapy available.[(20)] In Pakistan, an estimated 3,540 new drugs were registered between May 1, 1994 and February 29, 1996, based on official figures, or almost eight new drugs per

working day.[21] Roberto López, coordinator of the Latin American network of Acción Internacional para la Salud in Peru, notes that "if developing countries, with an 'open market' policy register as many products as the industry wants, it is going to be impossible to screen the corresponding promotional activities. At present, even the United States does not have the capacity to adequately control promotion of the products on its market."[22]

Successful regulation with effective monitoring and enforcement is expensive. The resources may not be available to developing countries; and industrialized countries facing fiscal restraints are unlikely to increase spending to ensure effective monitoring and enforcement. For example, in 1997, within a national governmental fiscal restraint programme, Canada's drug regulatory agency delegated control of OTC promotion to a private organization representing the advertising industry.[23]

The problem is compounded both by a lack of public awareness of the extent to which health care is being transformed by commercial interests, and by new and emerging strategies for drug promotion which lie outside of the scope of existing regulations. "Regulation will always lag behind the ingenuity of the advertising executives,"[24] comments Larry Sasich of the US Public Citizen Health Research Group.

Many new trends in drug promotion reflect the industry's success in finding loopholes in existing regulations to control drug promotion. A 1990 article by Morris and Banks, US FDA officials, listed five main techniques companies use to get around US FDA regulations, which they call "the five advertising end-runs":

1) use of industry-sponsored scientific and educational activities;

2) basing claims for products on inadequate scientific evidence, for example open-label studies are used to support efficacy claims;

3) use of press releases and materials produced by public relations firms;

4) direct-to-consumer advertising

5) asking the FDA to preapprove promotion but then changing the promotional material that is disseminated to the medical profession or the public.[25]

Morris and Banks' article is unusual in that it provides a glimpse of a regulatory agency's frustration over company strategies commonly used to bypass controls. These are but some of the many large gaps in the regulation of drug promotion within national borders and beyond. Some have become apparent because of the recent flourishing of unregulated promotion in new media such as the Internet. Others are longstanding problem areas.

This paper will examine promotion targeting five main audiences:

- consumers
- prescribers
- pharmacists and drug sellers

- health care providers
- and researchers.

The theme of many of these examples is a deliberate blurring of boundaries between promotion and education on the one hand and the public and private sector on the other. With shrinking public budgets for health and social services, a new climate of “partnership” with industry has emerged without a great deal of examination of what these partnerships may mean. What are the implications for consumer health, access to appropriate health services, and the information on which treatment choices are based? What sort of measures are needed to prevent conflict of interest? Finally, as discussed in the conclusion to this paper, how can both new and traditional forms of drug promotion be effectively controlled in the interests of public health and consumer rights?

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