Blurring the Boundaries: Conclusion

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Unlike many other consumer products in the marketplace, medicines are powerful agents which have the ability to cause harm as well as benefit. Medicines cannot be defined simply as pharmaceutical products in pills, patches, injections or other delivery forms. The information accompanying drugs is a key "active ingredient" which enables them to be used effectively, in a way which maximizes potential benefits and minimizes potential harm. This information is not a secondary frill. Without appropriate information for prescribers and users on how to use it properly, even the highest quality state-of-the-art product is useless.

At a minimum, prescribers and users need to know:

- what health conditions a medicine has been shown to effectively treat;
- how its effects and price compare to other drug or non-drug treatments;
- the dose needed and how it should be taken;
- who should or should not use the drug (contraindications)
- other drugs or products to avoid when taking it (interactions)
- what common and rare adverse effects are possible and what to do if an adverse effect occurs.

The international pharmaceutical industry is rightly proud of the advances made in quality control of pharmaceutical production and chemical purity; unfortunately, as the many examples above indicate, it has much less to be proud of in the quality of the promotional information which accompanies medicines, whether it is in the form of print advertisements, sales representatives' presentations, booklets by sponsored patient organizations, news stories by journalists based on industry information, academic presentations by paid industry consultants, or many other activities.

Medicines continue to be promoted beyond when they are needed or have shown to be helpful and new, more expensive products are promoted where they bring no clear advantage. The potential health consequences for the consumer are not benign: treatment failures from the use of the wrong therapy; patients suffering unnecessary adverse effects; increases in antibiotic-resistant organisms; and the waste of patients' money and scarce national health resources.[(185)]

The worst excesses of misleading and unethical drug promotion continue to occur in developing countries, where regulation of the pharmaceutical market is weakest.[(186)] The multinational pharmaceutical industry has also penetrated rapidly into the transitional economies of Eastern Europe and Central Asia, often with few controls on promotional

excesses and with few non-commercial information sources available for doctors or the public.

All promotion by definition is information whose aim is to market a product and as such has an inherent bias towards showing the product in the best possible light. Globally, a huge imbalance in the financial resources available for promotional versus independent information exists. As a result consumers and prescribers are generally subject to a positive information bias: the benefits of medicine use tend to be exaggerated, the risks downplayed.

How can promotion effectively be controlled, to ensure that a more rational use of medicines is encouraged? Consumer advocates have been calling for stronger, effectively enforced controls on drug promotion for many years. To be effective such controls need to include pre-screening of printed promotional materials and active monitoring of other forms of promotion, such as the information provided by sales representatives.

Stronger controls are needed but are only one side of the picture. The other necessary step is educational: building critical awareness among consumers, the media and the health professions. This includes education on the principles of rational drug use, on how to ask the right questions about treatment options, on limits as well as benefits of drug treatment, and education which raises questions about commonly held misconceptions such as “newer is better”. Consumers also need access to independent comparative information on treatment options and, where they exist, guidelines for treatment of specific conditions.

This does not necessarily imply expanding the role of self-medication; it does recognize, however, that consumers have the right to know what options may be available and how they compare to one another. One argument against this approach is that the information will be too technical for consumers to understand, or that it may lead to faulty self-diagnosis. This rests on the one hand on a caricature of the stupid consumer; on the other of the incompetent doctor, unable to explain to patients in everyday language what is wrong with them and what treatments are possible. In each case, better health and drug information, in language an average person can understand, would simply build on existing skills and allow for meaningful conversations between doctors, pharmacists and patients about treatment options.

The second step needed is to build critical awareness about how drugs are marketed, to stimulate people to develop antennae for disguised promotion and a healthy dose of skepticism about claims for the latest wonder drugs. Medical and pharmacy educational curricula also need to be revised to include modules on drug promotion and critical appraisal. Tools for critical appraisal of health information could be taught in the schools; many of the principles are useful for all forms of advertising — cigarettes and perfumes as well as medicines. Simple questions such as who produced this information or funded this research and who stands to gain from it can provide a useful start.

Techniques such as academic detailing, in which representatives of an independent information source visit doctors and “sell” information on the relative advantages and disadvantages of different treatment options, have been found to be effective.[(187)] Academic

detailing is expensive to set up and requires well-trained detailers; this model may need to be modified to be economically feasible in many developing countries. Some of the principles of academic detailing could also be brought to public meetings and health education for consumers.

Ethical guidelines and codes of practice

Health professionals, patient groups, media associations, health care providers and researchers all need to ensure that adequate ethical guidelines govern their relations with the pharmaceutical industry. Model guidelines need to be developed and widely circulated to provide additional support. One question is how to include procedures for effective monitoring and enforcement. Codes of practice tend to be largely voluntary and are rarely enforced. They do carry some moral weight, however, in identifying practices a health profession considers to be unethical or undesirable.

Consumer and patient organizations can also develop strict quality criteria for health information materials and peer review procedures, to avoid unwittingly spreading promotional messages. Networks of patient groups may want to consider working with their member groups to develop a joint code of practice in a similar way to those developed by professional organizations.

International Support for Effective National Regulation

The WHO *Ethical Criteria for Medicinal Drug Promotion* provide a general framework for attention to health rather than commercial priorities and situating the control of drug promotion within a country's national health and drug policies. However, for the *Ethical Criteria* to be effective as a means to control drug promotion, more is needed than a few changes in wording: "Any amount of strengthening the *Ethical Criteria* and including the latest trends in electronic promotion, in my opinion will not help us at all," said Dr Balasubramaniam, pharmaceutical advisor for Consumers' International and Asian coordinator for Health Action International (HAI).[(188)] He was speaking about the continuing lack of effective implementation of the *Ethical Criteria* nine years after they were developed, and stressing the need for WHO to develop model legislation to govern drug promotion along a similar model to the International Code on the Marketing of Breastmilk Substitutes.

Such model legislation should be widely disseminated and regularly reviewed. WHO's role should also extend to providing technical assistance and detailed guidelines for national governments wishing to introduce and implement effective controls of drug promotion, and to assist governments in finding the necessary resources to adequately enforce these controls.

What is needed nationally?

- comprehensive legislation governing drug promotion;
- a broad legal definition of drug promotion which includes all activities intended to promote the sales of medicinal drugs;

- ongoing monitoring, effective sanctions and mechanisms to correct misinformation
- public provision of independent information for prescribers, consumers and drug sellers, particularly about the most common diseases and commonly used treatments

For regulation to function effectively it must:

- be enforced by a public or semiautonomous publicly funded body, with a basis in legislation and without financial links to the pharmaceutical industry;
- be fully accountable, ie have full transparency of operations, and include consumer representatives as well as representatives of health professionals, pharmacists and representatives of the general and medical media
- include pre-screening of advertisements and other promotional material and messages wherever possible and pro-active surveillance where it is not, such as within continuing medical education, activities of sales reps, etc.
- have an escalating scale of sanctions
- include strict provisions for corrective information, both for consumers and health professionals.

“Currently if a company uses misleading promotion then society rewards it via increased sales and so the staff may really believe that they have done the right thing,”comments Peter Mansfield of the Medical Lobby for Appropriate Marketing (MaLAM).[(189)] He suggests an escalating scale of punishments with deregistration of a company as a final option, particularly in cases where health is adversely affected.

One way to judge the effectiveness of sanctions is to look at the rate of repeat offenses by the same company, which would be expected to be low if sanctions provide an effective disincentive.

National regulation of promotion is hampered by the lack of transparency, accountability and consumer representation in drug regulation. All aspects of drug regulation, include control of drug promotion, need to be made much more accountable to the public, with much closer communication between regulators, consumers, health professionals and managers of health services introduced into decision-making procedures. Joel Lexchin of MaLAM, recommends regulating promotion through an independent body with a basis in legislation and the legal ability to enforce compliance to its code and to levy and enforce sanctions. Members of this board would represent a wide range of groups, including consumers, and member organizations would have some say in who was appointed to represent them.[(190)]

Agnes Vitry, also with MaLAM, points out that: “Another failure of existing systems to control drug promotion is their narrow focus on substantiation of promotional claims on the basis of approved data sheets without considering broader public health impacts.”[(191)] For example, promotion of new broad spectrum antibiotics threatens public health because if these products are used commonly as first choice antibiotics for common bacterial infections, resistance will develop rapidly. These products would contribute much more to health if they were kept on reserve, to be used in cases of resistance to antibiotics which

have been in use much longer or failure of conventional therapy.

Promotion of antidiarrhoeal drugs in developing countries may not contravene their approved labelling; however, it is likely to divert resources and attention away from effective treatment of childhood diarrhoea through oral rehydration. In Pakistan in 1990, pharmaceutical companies spent US$7.5 million promoting anti-diarrhoeal treatments, with over 90% of this money spent promoting anti-diarrhoeal drugs.[192] Companies which promote tranquilizers and antidepressant drugs with images of women are doing nothing to contravene the approved product labelling. However, they are likely to contribute to a well-documented problem of inappropriate prescribing of psychotropic drugs to women.

These examples point to the need not only to ensure that a balanced presentation of the information in approved data sheets is presented in promotional materials, but also for a broader vision of the health impact of promotional messages. National regulatory authorities may want to consider banning promotion of some categories of prescription drugs, such as antibiotics or antidiarrhoeals, and in certain cases banning promotion which targets specific population groups, such as women, children or the elderly.

How could effective regulation be financed?

A large barrier to effective regulation of drug promotion as well as provision of independent information is a lack of public funding available for these activities. Companies are not subject to the same constraints, since extra spending on marketing brings in extra sales and therefore revenues. One solution would be for countries to finance both regulation of drug promotion and provision of independent drug information by introducing a tax on each promotional product (ie per printed or broadcast advertising message; per sales representative, etc).

Health ministries and justice departments in developing countries often lack the resources to effectively control product quality, let alone promotional information. One way to facilitate controls is to limit the number of drugs marketed, based on the principles of WHO's Essential Drugs Policies.[193] US FDA officials have also highlighted the problem of overwhelming volumes of promotional materials, making effective monitoring difficult if not impossible.[194] For industrialized countries, limited drug lists based on essential drugs policies, could also help not only to rationalize therapy but to limit the volume of promotion to a more manageable level.

Many countries depend heavily on foreign multinational companies, both through direct exports and production by branch plants. Promotional activities should be subject to regulation in the company's country of origin, in other words the country where the company's head office is located, as well as the country in which a product is sold, regardless of where manufacturing occurs. Promotional materials and labeling should be required to be acceptable in both countries, ie to adhere to the highest of the two standards. This would put more of an onus on governments in industrialized countries to prevent messages with negative health consequences from being provided overseas by multinational companies with head offices in their country.

An additional means of cutting costs would be for drug regulatory agencies within a region to collaborate much more closely and for all promotional activities in the region to be subject to a joint regulatory procedure. This approach is especially suited to regions sharing a common medical tradition.

International monitoring

The Medical Lobby for Appropriate Marketing (MaLAM) is an international watchdog organization which monitors pharmaceutical advertising and sends letters to companies requesting information to back claims which are not supported scientifically and which may lead to negative health consequences. Internationally, one advertisement by a multinational company in a developing country is chosen per month. It is chosen on the basis of clearly negative health advice and unsupported claims. The letter sent to the company includes a critique of the advertisement and related review of the scientific literature, and requests information from the company supporting its claims or actions. MaLAM's global membership sends supporting letters and requests replies along a similar model to that used by Amnesty International.

MaLAM has had a number of important successes in obtaining agreement from companies to change their marketing practices for specific products. Although criticism of one advertisement or promotional activity per month is a drop in the bucket in comparison to the volume of misleading and unethical drug promotion, the message to multinational companies is important, that their activities in developing countries are being watched by health workers from around the world.

A similar type of model could be extended widely to cover many types of drug promotion in many regions of the world. It could also involve consumers and perhaps journalists as well as health professionals, particularly if it concerned direct-to-consumer promotion, disease-oriented "educational" campaigns, promotional media stories, information materials produced by industry sponsored groups, and other forms of promotion targeting consumers.

The model *La revue Prescrire* has spearheaded in France for ongoing monitoring of sales representatives by an anonymous network of doctors could also be expanded into a wider international activity. This could be based on the tools, approach and publication procedures already developed in France. It would allow both for national monitoring, a necessary prerequisite to enforcement of regulations governing the activities of sales representatives, and also to international comparisons, particularly when the same product is being launched and heavily promoted by a company in several countries.

Consumer, health and development groups within the global Health Action International (HAI) network are campaigning for better national and international policies to control drug promotion, and bringing attention to examples of promotion with messages which compromise public health. HAI groups have been especially active in bringing media attention to double standards in information provision by multinational companies. This has in some cases involved joint advocacy work and press campaigns by health organizations in different countries — often the company's country of origin and the developing or Eastern

European country in which unethical and/or misleading promotion is being carried out.

General recommendations:

These suggestions do not cover all of the ways in which drug promotion could be better controlled. However, they do point to a few key principles:

- Regulation of drug promotion should have a basis in legislation, and be carried out either directly by national governments or by legislated independent bodies with the authority to monitor and enforce compliance, including sanctions and corrective actions. Reliance on industry self-regulation alone is ineffective;
- Monitoring, enforcement and an escalating scale of sanctions are key to effective national regulation;
- The overriding principle by which promotional messages should be judged is their potential impact on health; this may require additional regulations forbidding or restricting promotion of specific classes of drugs and/or promotion targeting specific population groups;
- Consumers and health professionals need to be involved in setting and enforcing standards;
- Transparency and public accountability are needed, both on the basis for regulatory decisions, for example whether a suspected breach of regulations is upheld or not, and publication of detailed information on violations;
- There is a need for increased availability and funding of independent sources of information for both health professionals and consumers;
- Consumers and health professionals have a key role to play in promoting critical awareness and including critical appraisal of health and drug information in medical and pharmacy curricula and in secondary schools.

Chapter References

(185) Chetley A, Mintzes B, editors Promoting Health or Pushing Drugs? A critical examination of marketing of pharmaceuticals. Health Action International, Amsterdam, 1992.

(186) Lexchin J. Deception by design: pharmaceutical promotion in the third world. Consumers International, Malaysia, 1995.

(187) Lomas J. Retailing research: increasing the role of evidence in clinical services for childbirth. Milbank.Q 1994;71:439-475.

(188) Balasubramaniam K. Personal communication, 1997 July.

(189) Mansfield P. Personal communication, 1997 July.

(190) Lexchin J. Personal communication, 1997 Aug.

(191) Vitry A. Personal communication, 1997 Aug.

(192) Lexchin J. Pharmaceutical promotion in the third world. Journal of Drug Issues 1992;22(2):417-422.

(193) World Health Organization.The use of essential drugs. Model list of essential drugs. Ninth list, seventh report of the WHO expert committee, technical report series no. 867, 1997.

(194) Morris LA, Griffin JP. 1992 op cit.