

Blurring the Boundaries

by Barbara Mintzes

RECOMMENDATIONS

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.

SUMMARY OF RECOMMENDATIONS FOR SPECIFIC FORMS OF DRUG PROMOTION

Direct to consumer promotion of prescription drugs

For action by national governments:

1. Direct-to-consumer advertisements of prescription-only drugs should not be allowed, given the lack of evidence of health benefits and the serious potential for harm.
2. Legislation controlling promotion should apply equally to promotional activities disguised as education about drugs or diseases, including prohibition of direct-to-consumer prescription drug promotion where this applies. This will require clear definitions of promotional versus non-promotional information based on criteria such as:

- whether a manufacturer is the direct or indirect source of the information,
- whether information on a disease is linked to recommendations for drug treatment,
- whether disease risks are presented in a manner which could be construed as inciting the public to seek drug treatment,
- whether use of specific drugs is recommended,
- whether diagnostic testing is recommended which may lead to drug treatment,
- and whether all available drug and non-drug treatment options are discussed in a fair and balanced manner.

3. Regulatory authorities may wish to consider a tax on pharmaceutical sales which could be used to set up a blind trust to fund independent drug information for both health professionals and consumers, as well as patient groups and other non-profit and charitable health organizations. Such a trust should be administered by an independent board with full provisions for transparency, public representation and accountability.

OTC promotion:

For action by national governments:

1. Promotion of over-the-counter medicines should be subject to as strict -- if not stricter -- controls than prescription-only drugs, as these products are often bought and used without the advice of a health professional.
2. This information should be presented in a balanced manner, bringing the reader's attention equally to claims about benefits and warnings about risks.
3. All promotional claims about health effects must include validated up-to-date scientific evidence to back those claims.
4. All advertising for OTC drugs should include the following information, presented legibly or audibly. Information should be presented in everyday language and at a low enough literacy level for consumers to understand, and include explanatory graphics where appropriate:
 - the name of the active ingredient(s), INN or approved generic name
 - the brand name
 - the 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 drug reactions
- precautions, contraindications and warnings
- major interactions
- documented degree of effectiveness (difference in treatment success between those taking the medicine and those not using it in placebo-controlled clinical trials)
- name and address of manufacturer or distributor
- reference to scientific literature to back promotional claims.

5. Information on risks and benefits should be presented in everyday language, with graphics where appropriate, and at a low enough literacy level for most of the public to understand.

6. Presently, consumers can obtain information only on expected benefits of OTC drugs before purchasing them; information on risks is generally included only in package inserts which they see after buying a drug. Consumers need pre-purchase access to full, comparative information.

Promotion of herbal remedies and dietary supplements:

For action by national governments:

1. Health claims should only be allowed if evidence exists to back them, with up-to-date scientifically validated documentation provided to back all claims.
2. Where there is traditional experience with a natural remedy but no scientifically validated evidence to support its use, a warning message stating this should be mandatory.
3. If health claims are made for a product, information requirements should follow the guidelines suggested under point 4 of the recommendations for OTC drug promotion.
4. Information on expected benefits and potential risks should be presented in a balanced manner and should be available to consumers before a product is purchased.

Industry sponsorship of patient and consumer groups

For actions by patient and consumer groups:

1. Associations, alliances and networks of patient and consumer health groups as well as individual organizations should consider developing and disseminating ethical guidelines and/or codes of practice on industry sponsorship. These should include provisions for accountability to the organization's membership and the public,

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transparency, and exclusion of potential funding sources if conflict of interest is a problem, ie if a funder's financial interests are linked to the organization's membership and/or activities.

2. Blind trusts could be considered as a way consumer groups could accept money from a variety of private sources, which might or might not include the pharmaceutical industry, without compromising their independence.

3. Consumer groups should list sources of funding in all of their publications and at public events, and should have a written policy on quality assurance of information materials, including a procedure for peer review by individuals or organizations who are independent of the pharmaceutical industry.

For action by national governments:

1. Any informational and educational materials whose production is funded by the pharmaceutical industry should be subject to the same regulations governing drug promotion as materials directly produced by a company, including requirements for fair balance, accuracy, avoidance of false or misleading statements or promotion of unapproved uses, an adequate discussion of risks as well as benefits, and pre-screening where this is a legal requirement for pharmaceutical advertising.

2. Regulatory guidelines for sponsored symposia and other meetings targeting health professionals should also apply to public meetings and educational events.

Internet promotion

For action by national governments and international fora:

1. International agreements are needed to regulate product promotion and sales on the Internet as this form of promotion crosses national borders. International harmonization procedures for drug regulation should include agreements covering drug promotion based on guidelines in line with the WHO *Ethical Criteria*. This would create a forum for regulation of cross border promotion, including Internet promotion.

2. Commercial or educational information originating from a commercial source should be required to have the company's name clearly and prominently stated on each screen, whether a company has directly provided the information or paid another party to do so.

3. Direct links from a company's home page should be regulated as if they originated from the company.

4. Advertisements posted internationally on the Internet need to be considered as DTC advertisements as they reach the general public. An on-screen proviso that information is "for US viewers only" or "for health professionals only" is inadequate unless companies wish to add some sort of password mechanism to limit viewing to those to

whom it can legally advertise. All posted advertisements should be required to meet similar regulatory standards for content as advertisements in other media, including the need for balanced information on risks and benefits, backing of claims with validated scientific evidence, etc.

5. Educational information provided by pharmaceutical companies on the Internet and in other media about health conditions their products treat should be subject to the same requirements for balance, disclosure of risks as well as benefits, and backing with validated scientific evidence as direct product advertising. In other words claims about the need for treatment should be subject to similar regulation as other forms of drug promotion.

Sales representatives

For action by national governments:

1. National legislation controlling drug promotion should include explicit provisions for the type and balance of information which sales representatives provide to doctors during each visit. This should be based on the official data sheet and should include a balanced presentation of potential benefits and risks, including the generic name, indications, dosage and administration, side effects, contraindications and warnings.

2. Ongoing monitoring of sales representatives' visits is needed, with effective sanctions for inaccuracies and omissions. This could be based on randomized sampling of visits funded through a fee levied on companies and based on the size of their sales forces.

For action by professional medical and pharmaceutical associations:

3. Monitoring the quality of information provided by sales representatives, as described above, should also be a responsibility of professional medical and pharmaceutical associations.

For action by academic institutions:

4. Curricula for medical education should include sessions on how to judge the content and accuracy of information provided by medical representatives.

For action by health service providers:

5. Individual doctors and health services may wish to consider choosing not to see sales representatives, and to devote the time saved to consulting independent information sources assessing new and existing therapies. This can be part of an initiative for a "promotion-free zone."

6. Hospitals, clinics and other health facilities can also introduce guidelines to regulate the activities of sales representatives within their premises. Initiatives which have proved useful include: pre-approval of sales rep visits to a health facility; not allowing

reps into patient care areas; permitting only group presentations, and not allowing sales reps to speak at educational events.

Sales and provision of prescribing data

For action by professional pharmacy associations:

1. Pharmacists should not be allowed to sell personal prescribing information; this information reflects a confidential interaction between doctor and patient and should not be sold to a third party without the expressed written consent of both doctor and patient, whether the doctor's name, the patient's name or both are included.

For action by national governments:

2. National and regional information on drug utilization and sales, based on anonymized data, should be publicly available to interested consumers and health professionals as it can be used to develop and analyze the impact of health policies.

Formulary development, health maintenance organizations

For action by public and private health service providers:

1. Health care providers, patients and payers need independent comparative information on pros and cons of all available treatment options in order to ensure both that potential health and monetary costs do not outweigh potential benefits, and to be able to choose the least costly among equivalent alternatives. This could be provided through public financing of the development, regular updating and wide dissemination of treatment guidelines.

2. Financial independence should be a prerequisite for committee membership to develop formulary lists for Health Maintenance Organizations (HMOs) and other health care providers. Strict conflict of interest criteria should be developed, as well as full transparency, public accountability and consumer representation on formulary committees.

Sponsorship of public health services

For action by national governments:

1. Health care is and should remain a public responsibility. Governments with insufficient funds to provide health services need to look for solutions without the potential for conflict of interest.

2. If funding of public health services from private health corporations is sought, measures such as joint funding of blind trusts can be used to ensure independent control over allocation of resources.

Sponsored research

(based on the recommendations of Bero and Rennie's and the Vancouver Group, see chapter 5)

For action by national governments:

1. National regulatory authorities should require publication of all studies submitted as part of the drug approval process.
2. National governments should set up registries for drug trials and require registration of all clinical trials when initiated (this could be a pre-condition linked to ethics review); with mandatory reports of results of all completed trials linked to the registry. This helps avoid the "positive publication bias" of only studies favouring a sponsor's drug being published.

For action by authors:

1. Financial and material support should be acknowledged and the nature of the support specified.
2. Authors should not enter into agreements that interfere with their control over the decision to publish.
3. Authors of research reports should be the researchers, not industry-supported writers.

For action by medical journal editors:

1. Influence of the sponsor if any on how the way the research has been carried out should be clearly stated: editors should require authors to describe the role of these sources, if any, in study design, collection, analysis, interpretation, and reporting. The type and degree of involvement of the supporting agency should be described in the methods section.
2. Editors should require disclosure of whether the sponsor controlled or influenced the decision to submit the manuscript for publication.
3. Industry funders should not be allowed to buy their way out of the peer review process by funding journals. This would require a more active role for journal editors in jointly setting minimum peer review requirements for publication of medical research results.

Consensus conferences

For action by professional associations, academic institutions and other sponsors of consensus conferences:

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1. Consensus conferences should only include participants without financial links to companies whose products are used to diagnose or treat the condition under discussion.
2. Proceedings and membership of consensus conferences should be fully transparent to ensure public accountability.
3. All consensus conferences should include consumer and patient representatives, again without financial links to the pharmaceutical industry.