DRUG PROMOTION

CIOMS/WHO meeting on Ethical Criteria for Medicinal Drug Promotion

CONCERN about the limited awareness and use of the Ethical Criteria for Medicinal Drug Promotion led the Forty-fifth World Health Assembly to request that WHO, in collaboration with the Council for Organizations of Medical Sciences (CIOMS), organize a meeting to consider approaches and mechanisms to improve their implementation world wide. The meeting, held in Geneva in November 1993, was attended by representatives of national drug regulatory agencies, the pharmaceutical industry, health professionals, consumer groups and scientific journals.

The major tasks of the consultation were:

- to examine the problems that surround inappropriate promotional practices and conflict with the Ethical Criteria for Medicinal Drug Promotion, with special reference to the situation in developing countries;
- to consider what further steps are required to gain a greater understanding of those problems and how they vary according to a country's social, economic, commercial and health development;
- to explore what concrete actions might be taken in the short, medium and long term;
- to forward a report of the meeting to the Director-General of WHO for his consideration for further action.

The recommendations from this meeting are far reaching and relate particularly to education and communication; the interface between promotion and regulation; and the development of national policies and international collaboration. Participants reinforced the leadership role of WHO, recognizing that it is centrally placed to develop dialogue on how advertising control can best be integrated into the process of drug registration.

THE RIGHT TO INFORMATION

Underlying all of the proposals from the consultation is the overriding ethical principle of the right to be informed. Participants acknowledged that patients and prescribers have the right to information about medicinal drugs that is factual and supportable, and that provides specific directions for appropriate drug use and monitoring of therapy. Positive claims for a product must always be balanced by information concerning side effects, contraindications, warnings etc. The information should be provided in such a way as to allow patients to decide whether they wish to receive the therapy.

RECOMMENDATIONS FOR FURTHER ACTION

Education and communication

Participants saw these as vital elements in achieving the goals set out in the Criteria and proposed that WHO, along with other interested groups, should develop and disseminate educational materials nationally and internationally. It was felt that currently these are limited in terms of both their appropriateness and availability for the varied audience which needs to be reached, including the general public, sales representatives, marketing managers, health personnel and the media.

A therapeutic guideline produced by WHO

WHO should also alert Member States to the important role of educational institutions and assist them in educational programme development. Raising awareness of problems associated with drug promotion and developing critical appraisal skills concerning all information about drugs, should be an integral component of undergraduate and continuing education for health personnel.

WHO should take a leading role in promoting therapeutic guidelines for prescribers that provide independent, comparative information and include explanations of the Ethical Criteria.

Consideration should be given to the difficulty in accessing the various types of materials useful to those trying to implement the Ethical Criteria more effectively. These include existing legislation on drug promotion and materials available from drug regulatory agencies. It was recommended that interested parties, such as industry and consumer groups, explore ways to establish a clearing house system for these materials.

Studies in relation to the ethical criteria and drug regulation and promotion

The meeting recommended that WHO, in consultation with other concerned groups, should periodically review the Ethical Criteria, decide how to monitor their implementation, continue to develop performance indicators in this area, and consider what action should be taken when the Criteria are not complied with.

In consultation with others, WHO should look into the possibility of initiating studies of the content, flow and use of information relating to medicinal drugs. People need accurate, independent and comparative drug information. But the meeting felt that sometimes information is inappropriate, or even when appropriate it does not always reach those who could use it. Another concern was that potential user may not have the capacity to absorb and benefit from the information.

National policies and actions

The Ethical Criteria should be an integral part of all national drug policies, a vital element of which should be legal and procedural arrangements for ensuring the appropriate use and promotion of medicinal drugs. The establishment of national drug policy committees can facilitate the creation of responsible national pharmaceutical programmes and should involve government, consumers, health professionals and manufacturers.

The consultation called for the creation and strengthening of national pharmaceutical industry associations which would promote corporate practices consistent with the Ethical Criteria.

WHO, Member States, consumers, industry associations, and national medical associations should try and ensure adherence to the guidelines laid down for the acceptable training and conduct of medical representatives and also ensure that industry symposia and meetings are educational rather than promotional.

An interactive combination of national regulation by governments together with self regulation by pharmaceutical companies, (backed by rigorously applied sanctions), can be a constructive arrangement in implementing the Criteria. The meeting also recognised the value of autonomous bodies to set ethical standards, review and/or clear promotional material and adjudicate complaints.

International collaboration

While national level regulations, procedures and other arrangements for promoting the criteria are essential, critical contributions are also needed at the international level. Participants urged greater cooperation among all groups concerned with improving health care through the rational use of drugs, in order to strengthen understanding of and compliance with the Ethical Criteria.

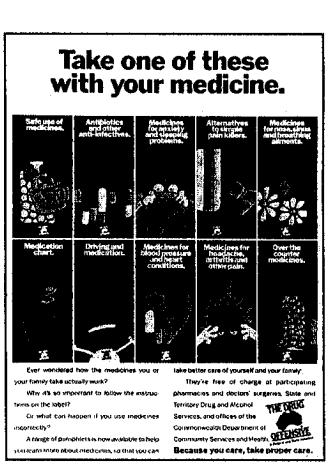
The meeting stressed WHO's central role in helping Member States establish and strengthen their programmes for ensuring the quality and rational use of drugs with the Ethical Criteria providing additional support for national drug policies. Those attending the meeting felt that further development by WHO of performance indicators, monitoring procedures and educational modules would assist in implementing the Criteria.

The International Pharmaceutical Manufacturers' Association (IFPMA) and the World Federation of Proprietary Medicine Manufacturers (WFPMM), national associations and local companies should continue to develop their own codes relating to the promotion of medicinal drugs in ways that are consistent with the Ethical Criteria, and exert their influence to encourage the formation and activities of national associations of pharmaceutical companies in their respective areas.

International, national and local consumer groups should continue in their key role of working with governments and industry to promote the implementation of the Ethical Criteria particularly pursuing studies of promotion methods, monitoring compliance with the Criteria, and working to create a critical awareness among consumers.

Participants recommended that scientific journals develop advertising guidelines which ensure compliance with the Ethical Criteria. (See box for an early response to this recommendation).

WHO, CIOMS and other interested parties, including donor organizations, should consider how these national and international interests and resources can be utilized more effectively in relation to the Ethical Criteria. Convening regional meetings to consider these issues was seen as one possibility.



Consumers too need access to drug information. Patient education pamphlets from the Australian Consumers' Association

THE FUTURE

There is no doubt that tensions exist between government regulators, industry and consumer advocates on a variety of matters, including drug promotion, but the challenge of the meeting was to capitalise on their common commitment and strengths. Those attending considered the consultation a success in bringing participants into substantial agreement on a number of issues and actions to be taken. Most importantly the right to information was accepted as a fundamental ethical principle and 19 recommendations for further action were made. The report of the meeting was presented to the 47th World Health Assembly in May by WHO's Director-General (see page 14).

It is clear that a great deal of work lies ahead if unethical drug promotion is to be eliminated. All those involved need persistence in pursuing key issues and continued agreement on collective action, based on the realisation that they have a growing responsibility for the well being of patients individually and the public collectively, the meeting concluded. ❑

Advertising in medical journals

The International Committee of Medical Journal Editors issued the following statement on advertising policy at its meeting in Chicago in August 1993. "Most medical journals carry advertising, and advertising generates income for owners of journals, but advertising must not be allowed to influence editorial decisions. Editors must have full responsibility for advertising policy, and readers should be able to distinguish readily between advertising and editorial material. Juxtaposition of editorial and advertising material on the same product or subject should be avoided wherever possible. Finally, editors should consider for publication all criticisms of advertisements".