WHO CRITERIA FOR MEDICINAL DRUG PROMOTION

UN Instrument

Adopted by the Thirty-ninth World Health Assembly, May 1986 in resolution WHA39.27

INTRODUCTION

1. Following the WHO Conference of Experts on the Rational Use of Drugs held in Nairobi in November 1985, WHO prepared a revised drug strategy which was endorsed by the Thirty-ninth World Health Assembly in May 1986 in resolution WHA39.27. This strategy includes, among other components, the establishment of ethical criteria for drug promotion based on the updating and extension of the ethical and scientific criteria established in 1968 by the Twenty-first World Health Assembly in resolution WHA21.41. The criteria that follow have been prepared in compliance with the above on the basis of a draft elaborated by an international group of experts.

OBJECTIVE

2. The main objective of ethical criteria for medicinal drug promotion is to support and encourage the improvement of health care through the rational use of medicinal drugs.

ETHICAL CRITERIA

3. The interpretation of what is ethical varies in different parts of the world and in different societies. The issue in all societies is what is proper behaviour. Ethical criteria for drug promotion should lay the foundation for proper behaviour concerning the promotion of medicinal drugs, consistent with the search for truthfulness and righteousness. The criteria should thus assist in judging if promotional practices related to medicinal drugs are in keeping with acceptable ethical standards.

APPLICABILITY AND IMPLEMENTATION OF CRITERIA

4. These criteria constitute general principles for ethical standards which could be adapted by governments to national circumstances as appropriate to their political, economic, cultural, social, educational, scientific and technical situation, laws and regulations, disease profile, therapeutic traditions and the level of development of their health system. They apply to prescription and non-prescription medicinal drugs ("over-the-counter drugs"). They also apply generally to traditional medicines as appropriate, and to any other product promoted as a medicine. The criteria could be used by people in all walks of life; by governments; the pharmaceutical industry (manufacturers and distributors); the promotion industry (advertising agencies, market research organizations and the like); health personnel involved in the prescription, dispensing, supply and distribution of drugs; universities and other teaching institutions; professional associations; patients' and consumer groups; and the professional and general media (including publishers and editors of medical journals and related publications). All these are encouraged to use the criteria as appropriate to their spheres of competence, activity and responsibility. They are also encouraged to take the criteria into account in developing their own sets of ethical standards in their own field relating to medicinal drug promotion.

5. The criteria do not constitute legal obligations; governments may adopt legislation or other measures based on them as they deem fit. Similarly, other groups may adopt self-regulatory measures based on them. All these bodies should monitor and enforce their standards.

PROMOTION

6. In this context, "promotion" refers to 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.

7. Active promotion within a country should take place only with respect to drugs legally available in the country. Promotion should be in keeping with national health policies and in compliance with national regulations, as well as with voluntary standards where they exist. All promotion-making claims concerning medicinal drugs should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. They should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or to give rise to undue risks. The word "safe" should only be used if properly qualified. Comparison of products should be factual, fair and capable of substantiation. Promotional material should not be designed so as to disguise its real nature.

8. Scientific data in the public domain should be made available to prescribers and any other person entitled to receive it, on request, as appropriate to their requirements. Promotion in the form of financial or material benefits should not be offered to or sought by health care practitioners to influence them in the prescription of drugs.

9. Scientific and educational activities should not be deliberately used for promotional purposes.

ADVERTISING

(a) Advertisements in all forms to physicians and health-related professionals

10. The wording and illustrations in advertisements to physicians and related health professionals should be fully consistent with the approved scientific data sheet for the drug concerned or other source of information with similar content. The text should be fully legible.

11. Some countries require that advertisements should contain full product information, as defined by the approved scientific data sheet or similar document, for a given period from the date of first promotion or for the full product life. Advertisements that make a promotional claim should at least contain summary scientific information.

12. The following list, based on the sample drug information sheet contained in the second report of the WHO Expert Committee on the Use of Essential Drugs[1] and appended for ease of reference, can serve as an illustration of the type of information that such advertisements should usually contain, among others:
    - the name(s) of the active ingredient(s) using either international nonproprietary names (INN) or the approved generic name of the drug;
    - the brand name;
    - 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, contra-indications and warnings;
    - major interactions;
    - name and address of manufacturer or distributor;
    - reference to scientific literature as appropriate.

13. Where advertisements are permitted without claims (reminder advertisements), they ought to include at least the brand name, the international nonproprietary name or approved generic name, the name of each active ingredient, and the name and address of the manufacturer or distributor for the purpose of receiving further information.

(b) Advertisements in all forms to the general public

14. Advertisements to the general public should help people to make rational decisions on the use of drugs determined to be legally available without a prescription. While they should take

1 WHO Technical Report Series, No. 722, 1985, p. 43.

account of people's legitimate desire for information regarding their health, they should not take undue advantage of people's concern for their health. They should not generally be permitted for prescription drugs or to promote drugs for certain serious conditions that can be treated only by qualified health practitioners, for which certain countries have established lists. To fight drug addiction and dependency, scheduled narcotic and psychotropic drugs should not be advertised to the general public. While health education aimed at children is highly desirable, drug advertisements should not be directed at children. Advertisements may claim that a drug can cure, prevent, or relieve an ailment only if this can be substantiated. They should also indicate, where applicable, appropriate limitations to the use of the drug.

15. When lay language is used, the information should be consistent with the approved scientific data sheet or other legally determined scientific basis for approval. Language which brings about fear or distress should not be used.

16. The following list serves as an illustration of the type of information advertisements to the general public should contain, taking into account the media employed:
    - the name(s) of the active ingredients(s) using either international nonproprietary names (INN) or the approved generic name of the drug;
    - the brand name;
    - major indication(s) for use;
    - major precautions, contra-indications and warnings;
    - name and address of manufacturer or distributor.

    Information on price to the consumer should be accurately and honestly portrayed.

MEDICAL REPRESENTATIVES

17. Medical representatives should have an appropriate educational background. They should be adequately trained. They should possess sufficient medical and technical knowledge and integrity to present information on products and carry out other promotional activities in an accurate and responsible manner. Employers are responsible for the basic and continuing training of their representatives. Such training should include instruction regarding appropriate ethical conduct taking into consideration the WHO criteria. In this context, exposure of medical representatives and trainees to feed-back from the medical and allied professions and from independent members of the public, particularly regarding risks, can be salutary.

18. Medical representatives should make available to prescribers and dispensers complete and unbiased information for each product discussed, such as an approved scientific data sheet or other source of information with similar content.

19. Employers should be responsible for the statements and activities of their medical representatives. Medical representatives should not offer inducements to prescribers and dispensers. Prescribers and dispensers should not solicit such inducements. In order to avoid over-promotion, the main part of the remuneration of medical representatives should not be directly related to the volume of sales they generate.

FREE SAMPLES OF PRESCRIPTION DRUGS FOR PROMOTIONAL PURPOSES

20. Free samples of legally available prescription drugs may be provided in modest quantities to prescribers, generally on request.

FREE SAMPLES OF NON-PRESCRIPTION DRUGS TO THE GENERAL PUBLIC FOR PROMOTIONAL PURPOSES

21. Countries vary in their practices regarding the provision of free samples

of non-prescription drugs to the general public, some countries permitting it, some not. Also, a distinction has to be made between provision of free drugs by health agencies for the care of certain groups and the provision of free samples to the general public for promotional purposes. The provision of free samples of non-prescription drugs to the general public for promotional purposes is difficult to justify from a health perspective. If this practice is legally permitted in any country, it should be handled with great restraint.

SYMPOSIA AND OTHER SCIENTIFIC MEETINGS

22. Symposia are useful for disseminating information. The objective scientific content of such meetings should be paramount, and presentations by independent scientists and health professionals are helpful to this end. Their educational value may be enhanced if they are organized by scientific or professional bodies.

23. The fact of sponsorship by a pharmaceutical manufacturer or distributor should clearly be stated in advance, at the meeting and in any proceedings. The latter should accurately reflect the presentations and discussions. Entertainment or other hospitality, and any gifts offered to members of the medical and allied professions, should be secondary to the main purpose of the meeting and should be kept to a modest level.

24. Any support to individual health practitioners to participate in any domestic or international symposia should not be conditional upon any obligation to promote any medicinal product.

POST-MARKETING SCIENTIFIC STUDIES, SURVEILLANCE AND DISSEMINATION OF INFORMATION

25. Post-marketing clinical trials for approved medicinal drugs are important to ensure their rational use. It is recommended that appropriate national health authorities be made aware of any such studies and that relevant scientific and ethical committees confirm the validity of the research. Intercountry and regional cooperation in such studies may be useful. Substantiated information on such studies should be reported to the appropriate national health authorities and disseminated as soon as possible.

26. Post-marketing scientific studies and surveillance should not be misused as a disguised form of promotion.

27. Substantiated information on hazards associated with medicinal drugs should be reported to the appropriate national health authority as a priority, and should be disseminated internationally as soon as possible.

PACKAGING AND LABELLING

28. Appropriate information being important to ensure the rational use of drugs, all packaging and labelling material should provide information consistent with that approved by the country's drug regulatory authority. Where one does not exist or is rudimentary, such material should provide information consistent with that approved by the drug regulatory authority of the country from which the drug is imported or other reliable sources of information with similar content. Any wording and illustration on the package and label should conform to the principles of ethical criteria enunciated in this document.

INFORMATION FOR PATIENTS: PACKAGE INSERTS, LEAFLETS AND BOOKLETS

29. Adequate information on the use of medicinal drugs should be made available to patients. Such information should be provided by physicians or pharmacists whenever possible. When package inserts or leaflets are required by governments, manufacturers or distributors should ensure that they reflect only the information that has been approved by the country's

drug regulatory authority. If package inserts or leaflets are used for promotional purposes, they should comply with the ethical criteria enunciated in this document. The wording of the package inserts or leaflets, if prepared specifically for patients, should be in lay language on condition that the medical and scientific content is properly reflected.

30. In addition to approved package inserts and leaflets wherever available, the preparation and distribution of booklets and other informational material for patients and consumers should be encouraged as appropriate. Such material should also comply with the ethical criteria enunciated in this document.

PROMOTION OF EXPORTED DRUGS

31. Ethical criteria for the promotion of exported drugs should be identical with those relating to drugs for domestic use. It is desirable that exporting and importing countries that have not already done so should use the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

Copies of the WHO Criteria for Medicinal Drug Promotion are available in English, French, Spanish, Russian, Chinese and Arabic from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price: Sw.fr.8.-/US$7.20 and in developing countries Sw.fr.5.60.

APPENDIX

Sample Drug Information Sheet[2]
Drug information sheets

Various types of information are needed by prescribers and consumers to ensure the safe and effective use of drugs. The following list is a sample that should be adjusted to meet the needs and abilities of the prescriber.

(1) International Nonproprietary Name (INN) of each active substance.

(2) Pharmacological data: a brief description of pharmacological effects and mechanism of action.

(3) Clinical Information:

(a) Indications: whenever appropriate, simple diagnostic criteria should be provided.

(b) Dosage regimen and relevant pharmacokinetic data:
- average and range for adults and children;
- dosing interval;
- average duration of treatment;
- special situations, e.g., renal, hepatic, cardiac, or nutritional insufficiencies that require either increased or reduced dosage.

(c) Contra-indications.

(d) Precautions and warnings (reference to pregnancy, lactation, etc.).

(e) Adverse effects (quantify by category, if possible).

(f) Drug interactions (include only if clinically relevant; drugs used for self-medication should be included).

(g) Overdosage:
- brief clinical description of symptoms;
- non-drug treatment and supportive therapy;
- specific antidotes.

(4) Pharmaceutical information:

(a) Dosage forms.

(b) Strength of dosage form.

(c) Excipients.

(d) Storage conditions and shelf-life (expiry date).

(e) Pack sizes.

(f) Description of the product and package.

(g) Legal category (narcotic or other controlled drug, prescription or non-prescription.

(h) Name and address of manufacturer(s) and importer(s).

2 Reproduced from *The use of essential drugs: second report of the WHO Expert Committee on the Use of Essential Drugs* (WHO Technical Report Series, No. 722, 1985, p. 43).