PAN AMERICAN NETWORK FOR DRUG REGULATORY HARMONIZATION (PANDRH)

ETHICAL CRITERIA FOR PROMOTING, ADVERTISING, AND PUBLICIZING PHARMACEUTICALS

In its regulatory activities related to promoting, publicizing, and advertising medicines[1], it is recommended that PANDRH members be guided by the following Ethical Criteria supported by and consistent with those already established by the World Health Organization, taking their own national policies and legislation into consideration.

1-BACKGROUND

The World Health Organization (WHO) implemented a strategy on drugs and established *Ethical Criteria for Medicinal Drug Promotion*[2], which support and promote public health protection through the rational use of medicines.

In view of the influence that promoting, advertising, and publicizing medicines has on those who take them and on their consumption patterns, as well as the subsequent impact on health systems and the harmful health outcomes that this can produce both individually and collectively, it has become necessary to improve, expand, and define ethical criteria to strengthen public health protection and safety concerning the risks associated with the use of medicines.

Within this framework, it is especially necessary to raise awareness and protect the most vulnerable segments of the population, such as children, the elderly, pregnant women, and the chronically ill.

2 OBJECTIVES

2.1 Supporting and promoting health care improvement through the rational use of medicines

2.2 Serving as a frame of reference for PANDRH member countries for the preparation and review of health policies and regulatory mechanisms to deal with the promotion, advertising, and publicizing of pharmaceuticals

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[1] *Translator's note: For* the purposes of this document, the terms **drug**, **medicine**, **pharmaceutical product**, and **pharmaceutical** are used interchangeably to refer to medicinal products intended for prophylactic, diagnostic, or therapeutic use, as stated on page 10 of the WHO document *Counterfeit Drugs: Guidelines for the development of measures to combat counterfeit drugs*. Department of Essential Drugs and Other Medicines, World Health Organization, Geneva, 1999. Available online at http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.1.pdf.

[2] Available online (accessed 27 May 2011).at www.who.int/entity/medicines/technical_briefing/tbs/Drug_Regulation_History_Present_Future.pdf

2.3 Promoting a culture of responsibility where consumer is valued

2.4 Benefiting consumers and society—never third parties—will be *the* fundamental objective of promoting, advertising and publicizing medicines

2.5 Broadening and heightening the responsibility of sectors involved in promoting, advertising, and publicizing pharmaceuticals

3 DOMAIN

3.1 The Ethical Criteria constitute a baseline for behavior in this area. They do not represent legal obligations and can be adapted by PANDRH member countries to national circumstances.

3.2 These criteria involve a variety of stakeholders: governments; the pharmaceutical industry; the advertising industry (advertising agencies and organizations that conduct marketing studies, among others); health workers involved in prescribing, dispensing, supplying, and distributing medicines; universities and other teaching institutions; professional associations; patient and consumer groups; and the professional or popular media.

3.3 For the purposes of this document, the ethical criteria apply to prescription drugs (i.e. medicines obtainable only with a doctor's prescription), over-the-counter drugs, phytotherapeutic or herbal products, and other products recognized by national legislation.

3.4 All promotion, advertising, and publicity should be developed in accordance with existing provisions in national health policies and the respective national legislation, taking into account this document on ethical criteria.

4 GENERAL PRINCIPLES

4.1 Pharmaceutical products are a social good; accordingly, it is hereby established that, without exception, they will be treated as health goods and not simply consumer goods.

4.2 Governments should foster and promote education among people who take medicines as well as the professionals involved in this area, with the goal of creating a thoughtful and critical attitude when faced with different types of promotion, advertising, and publicity for pharmaceuticals.

4.3 For the purposes of these ethical criteria, promotion is understood as all informative and persuasive activities on the part of manufacturers and distributors where the objective is to encourage the prescription, dispensing supply, procurement, or use of medicines; this is accomplished through different strategies, media, and types of communication (including the sponsorship of conferences, the provision of free samples, etc.). For the purposes of this document, publicity and advertising are included in promotional activities.

4.4 When promoting, publicizing, and advertising medicines, the information should be based on verifiable scientific evidence and should be independent, accurate, reliable, and true; it should also be up-to-date and not violate prevailing social values. Furthermore, it should not contain confusing statements that could lead to misinterpretation or omissions that could create health hazards. The information should be based on references to the literature that will be available upon request.

4.5 Only nonprescription, over-the-counter products can promoted, publicized, and advertised to the general public.

4.6 Any type of promotion, advertising, and publicity involving medicines should not exaggerate what can be expected from the product beyond what has been scientifically verified. Furthermore, it should not attribute to the product any therapeutic, nutritional, cosmetic, diagnostic, or preventive actions or properties—or those of any other nature—that have not been expressly recognized or approved by the health authorities.

4.7 Promoting, advertising, and publicizing nonprescription drugs for over-the-counter sale should not lead to indiscriminate, unnecessary, incorrect, or inappropriate use. Neither should they be presented as a means of achieving a given status in life or as food, cosmetics, or any other consumer good or as substitutes for proper rest, a balanced diet, and good hygiene. Similarly, there should be no suggestion that a food item, cosmetic, or any other product for nonmedicinal consumption has therapeutic action.

4.8 Promotion, advertising, and publicity for nonprescription drugs should not suggest that using them can delay or eliminate the need to seek care from a health professional and/or undergo diagnostic or rehabilitation procedures. To support the rational use of nonprescription drugs sold over the counter, consulting a health professional should be promoted, as well as reading the product insert and label.

4.9 In any advertisement for a nonprescription drug sold over the counter, the description of its indications and action should be made in everyday language, avoiding terms that will confuse or mislead the consumer. When technical or scientific information is used, it should be presented clearly, without exaggerating its results or implications.

4.10 Under no circumstances should it be stated that a medicine is harmless or safe, nor can it be suggested or stated that a particular drug is safer or more effective compared to others without verifiable scientific evidence.

4.11 When promoting, advertising, and publicizing medicines, statements must not be used that may result in inspiring fear or anxiety or that suggest that a person's health could be affected if he/she does not use the drug.

4.12 When promoting, advertising, and publicizing pharmaceuticals, information should be divulged in an equitable manner, describing both the benefits and the risks associated with their use, complying with current legislation, and encouraging their rational use.

4.13 When promoting, advertising, and publicizing medicines, there should be no use of messages, symbols, or images of any nature that might distort the information or lead to error or confusion about the origin, outcomes, benefits, characteristics, or indications approved by the health authorities. Neither can they be targeted to children, youth, or any vulnerable population.

4.14 Promoting, advertising, and publicizing prescription drugs available for sale only by prescription can be aimed exclusively at health professionals and should not lead to their irrational prescription or dispensing.

4.15 Educational and scientific activities (conferences, symposia, seminars, and others) should not be used deliberately for promotional purposes. Pharmaceutical companies should not offer incentives to professionals who prescribe or dispense drugs, and they in turn should not solicit incentives of any type.

4.16 In public and private health facilities, representatives of pharmaceutical companies should respect and not interfere with the activities of health professionals (medical consultations and the dispensing of medicines, etc.) or with those of patients; moreover, they should comply with the rules of these centers.

4.17 Promotional, advertising, and publicity materials should describe the basic characteristics of the medicine: active ingredient(s) and their respective concentrations; brand/patent name, name used in the country, and International Nonproprietary Name (INN); main indication, precautions, most common or serious adverse reactions, contraindications, and clinically relevant interactions and warnings, as well as the name and contact information of the manufacturer or distributor, as stated in the respective legislation.

4.18 In order to prevent addiction and dependency, the promotion, advertising, and publicity about psychotropic drugs, stupefacients, and narcotics cannot be aimed at the general public and will only be destined for health professionals via technical and scientific journals.

4.19 Printed matter, audiovisual, electronic/digital/virtual/online materials, or materials that in any way are aimed at both professionals and the general public must respect the conditions laid down in the preceding articles.

4.20 In addition to having complied with all the criteria described above, online promotion, advertising, and publicity should employ a technical, scientific, or professional approach. Under no circumstances shall the sale of medicines be included using this medium. Furthermore, measures will be adopted to ensure that promotion of this type is sent only to prescribers or dispensers.

4.21 Media owners (newspapers, radio, and television, etc.) who publish or broadcast advertisements and commercials should do so bearing in mind the recommendations made in these ethical criteria and respecting the provisions of national legislation in this matter.

5 OTHER COMPONENTS RELATED TO PROMOTING, ADVERTISING, AND PUBLICIZING MEDICINES

5.1 Samples of legal medicines can be provided to evaluate patients' response to the medicine, on request and only to the professionals who are prescribing and dispensing the drug.

5.2 Pharmaceutical representatives and advertising personnel must have appropriate training and act entirely in compliance with these ethical criteria, directing their activities only to health professionals and offering them full and impartial information about the medicines.

5.3 Pharmaceutical companies are responsible for any statements made, information provided, and activities carried out by their advertising representatives and agents.

5.4 Medical advertising representatives and agents should notify the science department of the pharmaceutical company they represent about any information they receive from the professionals they visit related to the use of the medicines they are involved in promoting, especially any information about adverse reactions that the people they visit communicate to them. The pharmaceutical company should notify the competent health authority either immediately or within the time frame established by current regulations.

5.5 The scientific content of meetings, symposia, and other events on the topic of pharmaceuticals should be their fundamental purpose; and in cases involving sponsorship or the receipt of financial support for such activities, the existence of any conflict of interest should be explicitly declared.

5.6 Any support provided to health professionals to participate in a national or international symposium or scientific activity should not be conditional on any obligation to advertise a pharmaceutical product.

5.7 Laboratories that manufacture medicines can award fellowships for professional development or participation in scientific activities only if the conditions of access to them and the procedures for selecting applicants for such grants employ equitable and transparent mechanisms and professionals are publicly notified in advance.