

Pan American Network on Drug Regulatory Harmonization

Working Group on Medicines Promotion

Ethical criteria for the promotion, advertisement, and publicity of medicines



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CONTENTS

Working Group on Medicines Promotion.....	v
1. HISTORY.....	1
2. OBJECTIVES	2
3. SCOPE OF APPLICATION	3
4. GENERAL PRINCIPLES	4
5. OTHER COMPONENTS RELATED TO MEDICINE PROMOTION, ADVERTISEMENT, AND PUBLICITY	7
6. RECOMMENDATIONS	8

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1. HISTORY

The World Health Organization (WHO) has developed a medicines strategy and established Ethical Criteria for Medicine Promotion, advertisement, and publicity,¹ to support and promote the health protection of citizens through the rational use of medicines.

Considering the influence of medicine promotion, advertisement, and publicity on users and their consumption habits, and consequently the effect on health systems and the potential harmful results on individual and collective health, there is a need to improve, broaden, and define ethical criteria to strengthen public health protection and reduce risks associated to medicine use.

Within this framework, it is particularly necessary to build awareness and protect the most vulnerable sectors of the population, such as children, the elderly, pregnant women, and persons with chronic diseases.

¹ WHO. Ethical criteria for medicinal drug promotion. 1988.

2. OBJECTIVES

- 2.1 Support and promote the improvement of health care through the rational use of medicines.
- 2.2 Suggest a reference framework to member countries of the PANDRH to design and review health policies and regulatory mechanisms for medicine promotion, advertisement, and publicity.
- 2.3 Promote a culture based on responsibility and respect for people's health.
- 2.4 Ensure that medicines promotion, advertisement, and publicity are mainly aimed to benefit users and society and not third parties.
- 2.5 Expand and strengthen the responsibility of sectors related to medicine promotion, advertisement, and publicity.

3. SCOPE OF APPLICATION

- 3.1** These ethical criteria are an indication of behavior and attitudes in this matter. Their application is not a legal obligation and member countries of PANDRH may adapt them to their own domestic circumstances.
- 3.2** These criteria involve various actors: governments; pharmaceutical industry; publicity industry (publicity agencies, market study organizations, etc.); health personnel participating in prescribing, dispensing, supplying, and distributing medicines; universities and other educational institutions; professional associations, groups of patients and consumers; and the specialized and general information media.
- 3.3** For the purpose of this document, the ethical criteria are applied to all products recognized as medicines by national laws, whether they are sold over the counter or through a prescription, including the phytotherapeutic and herbal medicinal products.
- 3.4** The materials, plans, strategies, and objectives for promotion, advertisement, and publicity must be designed in accordance to the national health policies and legislations of each country, while taking into account this set of ethical criteria.

4. GENERAL PRINCIPLES

- 4.1 Medicines are social public goods and therefore, with no exceptions, they should be treated as such, and not as simple consumption products.
- 4.2 Governments must promote and encourage the education of users and professionals involved in this topic, to create a conscientious and critical attitude towards the different types of medicine promotion, advertisement, and publicity.
- 4.3 For the purpose of these ethical criteria, promotion is conceived as all informative and persuasive activities used by manufacturers and distributors, with the aim of inducing the prescription, dispensation, supply, acquisition, or utilization of medicines, regardless of the communication strategies, means and vehicles used (including congress sponsoring, distributing free samples, and others). For the purpose of this document, publicity and advertisement are included within promotional activities.
- 4.4 The information contained in the promotion, advertisement, and publicity of medicines must be based on verifiable scientific evidence, it must be independent, accurate, reliable, and true; it must be updated and not in contradiction with the existing social values. Therefore, the information must not contain confusing or possibly wrongly interpreted statements or omissions that may lead to health risks. The information offered must be based on documents issued by the pertinent regulatory or health authorities, and backed by bibliographic references that should be available under request.
- 4.5 Only medicines sold over the counter can be the object of promotion, advertisement, and publicity targeted towards the general population.
- 4.6 No type of medicine promotion, advertisement, or publicity should exaggerate the expectations of the product, above and beyond scientifically proven facts. Furthermore, no actions of therapeutic, nutritional, cosmetic, diagnostic, or preventive properties, or any other type of property should be attributed to the medicines unless they have been clearly recognized or approved by health authorities.
- 4.7 The promotion, advertisement, and publicity of medicines sold over the counter should not induce their indiscriminate, unnecessary, incorrect, or inadequate use. These medicines should not be presented as a mean to achieve a certain status in life. Furthermore, they should not be publicized as a type of food, cosmetic, or any other consumption product, or as being able to substitute resting, a balanced diet, and hygiene. At the same time, they should not suggest that a certain type of food or cosmetic, or any other non-medicinal consumption product has a therapeutic action.

- 4.8** The promotion, advertisement, and publicity of medicines sold over the counter should not suggest that their use may delay or make it unnecessary to consult a health practitioner, or undergo diagnostic or rehabilitation procedures. In support to the rational use of medicines sold over the counter, the promotion should encourage the patient to consult a health professional and read the insert accompanying the product.
- 4.9** The description in an advertisement of the indications and the effects of a medicine sold over the counter should be expressed in a colloquial manner, without terms that may confuse or disorient the consumer. When presenting technical or scientific information, this should be expressed in a clear form, without exaggerating the results or implications of the medicine, thereby offering balanced information in relation to the risks and benefits of its use.
- 4.10** In no case can it be indicated that the medicine is innocuous or safe. At the same time, it cannot be suggested or indicated that a certain medicine is safer or more effective than others without verifiable scientific evidence.
- 4.11** In the promotion, advertisement, and publicity of medicines no expressions producing fear or anguish should be used, as well as no suggestions indicating that health may be affected if the medicine is not taken.
- 4.12** The information used in the promotion, advertisement, and publicity of the medicines should be disseminated in a fair manner, describing both the benefits and risks associated to their use, while complying with the local legislation and favoring the rational use of medicines.
- 4.13** The promotion, advertisement, and publicity of medicines should not include messages, symbols, or images of any nature that may distort, lead to errors or confusion regarding the origin, results, benefits, characteristics, or indications approved by health authorities. Furthermore, they may not be targeted to children and teenagers, or any other vulnerable population.
- 4.14** The promotion, advertisement, and publicity of prescribed medicines may only be aimed at health professionals and should not induce their irrational prescription or dispensing.
- 4.15** Educational and scientific activities (congresses, symposia, seminars, and others) should not be used deliberately for promotional purposes.
- 4.16** The pharmaceutical industry should not offer incentives to professionals in charge of prescribing or dispensing medicines, and they should not request or receive incentives of any type.

- 4.17** Representatives of pharmaceutical companies should respect, and not interfere in the activities of the health professionals (medical actions or medicine dispensing, etc.) or of the patients, whether in public or private health facilities, and must comply with the regulations established in those centers.
- 4.18** Promotional, advertisement, and publicity materials should show the essential features of the medicine: the active principles it contains and their concentrations, the commercial name or brand, the international nonproprietary names (INN) or national denomination, its main indication, precautions, most frequent or severe adverse events, contraindications, clinically relevant interactions and warnings, manufacturer's or distributor's name and how to contact them, respecting the local legislation.
- 4.19** The promotion, advertisement, and publicity for psychotropic medicines and narcotics cannot be targeted at the general public and will only be aimed to health professionals in scientific and technical journals.
- 4.20** Printed, audiovisual and electronic materials—whether they are digital, virtual or through Internet—aimed at professionals as well as the general public, and regardless of the medium used, should respect the conditions expressed in the preceding sections.
- 4.21** Medicine promotion, advertisement, and publicity through Internet—including the social networks—while based on all the criteria described above, should also present a technical, scientific, or professional approach. They should under no circumstances include medicine sales through the web. Moreover, measures will be taken for disseminating this type of actions only to the personnel directly related to prescribing or dispensing the medicine.
- 4.22** The owners of the mass media, such as newspapers, radio, television, Internet services—including the social networks—among others, who disseminate medicines advertisements must follow these recommended ethical criteria and respect the regulations established in the national legislation on this topic.
- 4.23** In no case could there be any promotion, advertisement, or publicity actions that exaggeratedly exalt masculinity or femininity of the target population, in a deceitful manner, being detrimental to the dignity of the gender involved, or containing humiliating or discriminating elements to the human condition due to sex, age, race, social condition, sexual preference, health condition, or others.
- 4.24** No actions may be taken in any case for the promotion, advertisement, or publicity of raw materials, semi-manufactured products, master formulas, or galenic preparations.

5. OTHER COMPONENTS RELATED TO MEDICINE PROMOTION, ADVERTISEMENT, AND PUBLICITY

- 5.1 Samples of medicines that are legally available may only be distributed, after submitting a request, to professionals prescribing them and pharmacists for the evaluation of the adaptation of the patient to the medicine.
- 5.2 The representatives and advertisement agents of pharmaceutical companies must be properly trained, strictly follow these ethical criteria, aim their activity only to health professionals, and offer complete and unbiased information on the medicines.
- 5.3 Pharmaceutical companies are accountable for the statements, information, and activities of their representatives and advertisement agents.
- 5.4 Medical representatives and advertisement agents should notify the scientific service of the pharmaceutical company they represent on any information regarding the use of the medicine they are in charge of promoting, which is received from visits to health professionals, particularly when dealing with adverse reactions. The pharmaceutical company should report this to health authorities immediately or in the time periods established by the local norms.
- 5.5 The main purpose of the meetings, symposia, and other events on medicines should be of scientific content, and, if there is a sponsor or financial support for these activities, the existence of a possible conflict of interest should be clearly stated.
- 5.6 Any support offered to health professionals for their participation in a national or international symposium or scientific activity, should not be determined by the obligation of promoting a medicinal product or pose any type of pressure to prescribe it.
- 5.7 Medicine producing laboratories may only offer fellowships for professional advancement or participation in scientific activities when professionals have been informed publicly on the conditions for application and the selection process for candidates, using fair and transparent mechanisms.

6. RECOMMENDATIONS

The members of the Pan American Network for Drug Regulatory Harmonization (PANDRH) are recommended to design the guidelines for regulatory actions regarding promotion, advertisement, and publicity of medicines according to the ethical standards presented in this document, taking into account their domestic policies and laws. These criteria are supported by, and correspond to, those established by the World Health Organization (WHO).

