

Guidelines on Ethical Promotion of Medicine, 2007

(Unofficial document; official in Nepali Version)

Introduction

The ethical promotion of medicine is vital to the pharmaceutical industry's mission of helping patients for better healthcare. Ethical promotion helps to ensure that healthcare professionals have access to information they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.

The pharmaceutical industry has an obligation and responsibility to provide accurate information about its products to healthcare professionals in order to establish a clear understanding of the appropriate use of medicines. Through the effective implementation of this guideline, it is expected to establish ethical promotional practices throughout the country in alignment with acceptable international norms and codes.

There is evidence that drug utilisation problems are increasingly encountered in many developing countries due to unethical practices of medicine promotion. Recently Graduate Pharmacists' Association -Nepal (GPAN) has conducted a study on promotional practices in Nepalese pharmaceutical market in collaboration with DDA and World Health Organization (WHO). The findings were presented in a seminar on 20 Magh, 2063 (3 February, 2007). The study results indicated the need for implementation of guidelines on ethical promotion. GPAN developed the guideline, based on Ethical Criteria for Medicinal Drug Promotion (World Health Organization, Geneva 1988) and Code of Pharmaceutical Marketing Practices, (2006 Revision) (International Federation of Pharmaceutical Manufacturers Associations (IFPMA)). The stakeholders discussed on the guidelines and formed a committee to revise the draft on the basis of the comments provided during discussion. Draft thus modified, with some editing from DDA, was sent again to stakeholders on 23 Jestha 2064 (6 June 2007) for further comment. The guideline is finalised after incorporating relevant comments received and has been issued from the department for implementation on 32 Asadh 2064 (16 July 2007). With some experience on implementation of the guideline, it will be approved as "Code on Sales Promotion of Medicine" (औषधि विक्री प्रवर्द्धन संहिता) within Drug Registration Regulation, as per Clause 40 of the Drug Act 1978.

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1. Objective

- 1.1 The objective of this guideline is to promote ethical promotion of medicine to support and encourage the improvement of healthcare through the rational use of medicine and discourage unethical practices.

2. Implementation of the Guideline

- 2.1 This guideline is applicable to all medicines sold in Nepalese market. It applies to prescription and non-prescription medicines (over-the-counter drugs). They apply to all systems of medicine available in the country, and to any other product promoted as a medicine. The guideline is applicable to the pharmaceutical industry (manufacturers, distributors and retailers); the promotion industry (advertising agencies, market research organizations etc.); healthcare personnel involved in the prescription, dispensing, supply and distribution of medicines; 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 this Guideline as appropriate to their spheres of competence, activity and responsibility. They are also encouraged to take the Guideline into account in developing their own sets of ethical standards in their own field relating to ethical promotion of medicine. All these bodies should monitor and enforce their standards.

3. Promotion

- 3.1 In this guideline, “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 medicine.
- 3.2 Active promotion should take place only with respect to medicine legally available in the country. Promotion should be in keeping with National Drug Policy and in compliance with Drug Act and regulations, as well as with voluntary standards where they exist. All promotion-making claims concerning medicine 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 medicine use or to give rise to undue risks. Claims for therapeutic indications and conditions of use must be based on valid scientific evidence and include clear statements with respect to side effects, contra-indications, and precautions. 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.
- 3.3 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 (including the deal, bonus and promotional schemes) should not be offered to or sought by health care practitioners and retailers to influence in the prescription or sale of medicine.

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

3.5 Information to physicians and health-related professionals

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

3.5.1. Information that make a promotional claim should at least contain summary scientific information. Information 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 all the excipients and their role in the dosage form;
- 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, and distributor, where applicable;
- Reference to scientific literature as appropriate.
- Date of production of the information;

3.6. Information to the general public

3.6.1. Information to the general public should be available as information leaflet or insert. Such information leaflet made available from the pharmacy should help people to make rational decisions on the use of over-the-counter medicines. While they should take account of people's legitimate desire for information regarding their health, they should not take undue advantage of people's concern for their health. While health education aimed at children is highly desirable, medicine information should not be directed at children. The information 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 medicine.

3.6.2. 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.

3.6.3. The media employed should be considered when providing information to the general public. The following list serves as an illustration of the type of information:

- 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;
- Other relevant information supporting rational use of medicine, including *Anupana* and *Sahapana* in case of Ayurvedic medicine;

- Name and address of manufacturer or distributor.

3.6.4. Information on price to the consumer and change of price should be informed to DDA.

4. Advertisement

4.1. Prescriptive drugs should never be advertised in any form of printing or electronic media targeting the general public. However, the company can inform the prescribers about the introduction of their brand (including its strength and dosage forms) in the market in allied professional bulletins or technical publications.

4.2. The provision of advertisement could be relaxed for OTC drugs but the information to be given in the advertisement should follow the instructions given in clause 4.6 and the text of the advertisement to be approved from DDA before going to the media.

5. Company Procedures and Responsibilities

5.1. Pharmaceutical industries should develop a manual on promotion of medicine to ensure full compliance with this guideline and to review and monitor all of their promotional activities and materials. A designated company employee, with sufficient knowledge and appropriate scientific or healthcare qualifications should be responsible for approving all promotional communications.

5.2. Manufacturer and distributors should have policy not to provide any kind of inducement in cash or kind, including but not limited to, free medicines to prescribers or dispensers or retail pharmacy as a promotional practice.

6. Medical Representatives

6.1. Medical representatives of pharmaceutical industry represent both their company and the pharmaceutical industry as a whole in the eyes of healthcare practitioners. They are the main point of contact between the pharmaceutical industry and other partners in healthcare sector. For this reason, the industry should establish and maintain high standards in the recruitment and selection of medical representatives, to ensure that well-qualified people are hired. Medical representatives should be science or applied science graduates.

6.2. Supervised training must be provided as per company's training manual developed prior to the recruitment to enable the persons to become familiar with and carry out their responsibilities. This training will require new employees to acquire both technical and scientific information on company products, as well as knowledge of the ethical principles and standards of conduct set out in this guideline.

6.3. From time to time, the companies shall conduct refresher courses for medical representatives. Companies should also encourage all medical representatives to take courses of study and self-improvement.

6.4. Medical representatives must display the highest professional and ethical standards at all times. Medical representatives are expected to understand and abide by established codes of conduct.

- 6.5. Medical representatives must provide full and factual information on products, without misrepresentation or exaggeration. Medical representatives' statements must be accurate and complete; they should not be misleading, either directly or by implication. Their assertions must be scientific and should not vary in any way from the official product monograph.
- 6.6. Company management shall work with representatives on a regular basis to ensure appropriate information exchange occurs regarding code of conduct and information on products.
- 6.7. Employers are responsible for the basic and continuing training of their representatives. Employers should also be responsible for the statements and activities of their medical representatives.
- 6.8. Under no circumstances shall medical representatives pay a fee in order to gain access to a healthcare practitioner. They 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.
- 6.9. The foreign companies exporting their products to Nepal should either open their office in Nepal or the importer is made responsible on their behalf. Name of the chief of the marketing of domestic as well as foreign companies must be provided to the DDA and any change of person should be notified as soon as possible.

7. Free Samples of Medicine for Promotional Purposes

- 7.1 Free samples of legally available medicine may be provided in modest quantities to prescribers, generally on request. Free samples normally should be labelled as "Physician's Sample" and price should not be printed on it. Record of distribution of such samples should be maintained.

8. Symposia and Other Scientific Meetings

- 8.1. The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings for healthcare professionals organised or sponsored by a pharmaceutical industry should be to inform healthcare professionals about products and/or to provide scientific or educational information. Their educational value may be enhanced if they are organized by scientific or professional bodies.
- 8.2. The fact of sponsorship by a pharmaceutical manufacturer or distributor should clearly be stated in advance, at the meeting and in any proceedings of the meeting. The proceedings 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.
- 8.3. No stand-alone entertainment or other leisure or social activities should be provided or paid for by the industry or distributor.

9. Sponsorship

- 9.1 The pharmaceutical industry may sponsor healthcare professionals to attend symposia and other scientific meetings provided such sponsorship is in accordance with the following requirements:
- Sponsorship to healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees;
 - No payments are made to compensate healthcare professionals for time spent in attending the symposium; and
 - Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend or promote any pharmaceutical product.
- 9.2 Companies should not pay any costs associated with individuals accompanying invited healthcare professionals.
- 9.3 Payments of reasonable fees and reimbursement of out-of-pocket expenses, including travel and accommodation, may be provided to healthcare professionals who are providing genuine services as speakers or presenters on the basis of a written contract with the company at the symposium or meeting.
- 9.4 Payments in cash or cash equivalents (such as gift certificate) must not be offered to healthcare professionals. Gifts for the personal benefit of healthcare professionals (including, but not limited to, music CDs, DVDs, electronic items etc) must not be provided or offered.
- 9.5 Any support provided to individual health practitioner or organization should be transparent.
- 9.6 Promotional aids or reminder items may be provided or offered to healthcare professionals and appropriate administrative staff, provided the gift is of minimal value and relevant to the practice of the healthcare professional.
- 9.7 Items of medical utility may be offered or provided free of charge provided that such items are beneficial to the provision of medical services and for patient care.
- ## **10. Post-Marketing Scientific Studies, Surveillance and Dissemination of Information**
- 10.1 Post-marketing scientific studies for approved medicine are important to ensure their rational use. Approval for such research should be obtained from Nepal Health Research Council (NHRC) and/or Department of Drug Administration (DDA) where necessary and relevant scientific and ethical committees confirm the validity of the research. Inter-country and regional cooperation in such studies may be useful. Substantiated information on such studies should be reported to the appropriate national health authorities.
- 10.2 Post-marketing scientific studies and surveillance should not be misused as a disguised form of promotion.
- 10.3 Substantiated information on hazards associated with medicine or adverse drug reactions (ADR) should be reported to the DDA as a priority.

11. Packaging and Labelling

- 11.1 Appropriate information being important to ensure the rational use of medicine, all packaging and labelling material should provide information consistent with Drug Act and regulations and standards set by Department of Drug Administration. Any wording and illustration on the package and label should conform to the principles of ethical criteria enunciated in this guideline.

12. Information for Patients: Package Inserts, Leaflets and Booklets

- 12.1 Adequate information on the use of medicine should be made available to patients. Such information should be provided by physicians or pharmacists or health professionals whenever possible. When package inserts or leaflets are required by regulations, manufacturers or distributors should ensure that they reflect only the information that has been approved by DDA. If package inserts or leaflets are used for promotional purposes, they should comply with the ethical criteria enunciated in this guideline. 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.

- 12.2 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 guideline.

13. Promotion at Hospital Pharmacies

- 13.1 Drug and Therapeutics Committee (DTC) or similar committee of the hospital should develop code for promotion of medicine by the pharmaceutical industries at the hospital. Pharmaceutical industries and medical representatives should abide by the code.

14. Implementation of the Guideline

This Guideline will be implemented from 1 Shraavan, 2064 (17 July, 2007). DDA will monitor the implementation of this Guideline. DDA may develop procedures, processes and Standard Operating Procedures for monitoring the implementation.