

STATEMENT OF GENERAL PRINCIPLES

High standards of marketing are good for our business, our industry and are in the best interests of patients. The signatories to this code are committed to making all efforts to ensure the code is in conformity with generally recognized international standards.

I. OBJECTIVES:

- U To provide an enforceable code of marketing practices that is broad in scope, specific, consistent with highest ethical standards and is applicable to all pharmaceutical companies and all prescription medicines.
- U To ensure the highest ethical standards as well as all legal requirements are applied during all interactions with healthcare professionals
- U To reinforce our intention that our interactions with healthcare professionals are to benefit patients and to enhance the practice of medicine.

II. STATEMENT OF PRINCIPLES

1. Companies have an obligation and responsibility to provide accurate, balanced and fair information about its prescription drugs to health care providers.
2. Companies have a shared responsibility together with health care providers to provide accurate, balanced, and understandable information about their medicines to patients.
3. The pharmaceutical industry derives its responsibility from its knowledge and experience in the development of these medicines.
4. Education and information are essential to establish understanding of the appropriate use of prescription medicines.
5. All marketing activities should be conducted in accordance with clear, measurable and enforceable standards.
6. Promotional information shall be designed to help health care providers improve service to patients, and shall conform to the letter and spirit of all relevant national laws and regulations.
7. Standards of ethical behavior shall apply equally to marketing of prescription medicines in all countries, regardless of the level of development of their economic and health care systems.

8. Our relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education.

9. Companies have the obligation to maintain appropriate internal and external procedures to ensure full compliance with the specific guidelines of the code.

III. SPECIFIC GUIDELINES

PROMOTION

For the purpose of this document, promotion is a general term referring to all activities and communications designed to educate and inform health care providers, patients and the general public about prescription medicines, their uses, and the diseases or conditions for which they are intended.

Claims should not be stronger than scientific evidence warrants, and every effort should be made to avoid ambiguity.

1. Content:

- a) No public communication shall be made with the intent of promoting a prescription drug for any use until the marketing of such medicine for such use has been authorized by the appropriate government authority.

NOTE: this provision is not intended to abridge the right of the medical and scientific community and the public to be fully informed concerning scientific and medical progress. Nor is it intended to restrict a full and proper exchange of scientific or general communications media, except where specifically prohibited by law.

b) General

All advertising and promotional materials should or must be in accordance with approved labeling in the country of origin.

All advertising

All advertising appearing in print must include:

- the name of the product (normally the brand name);
- the active ingredients, using an approved name where one exists;
- the name and address of the company or its agent responsible for marketing the product.

Full advertisements

Full advertisements are those which include promotional claims for the use of products. In addition to the requirements in section 1b above, full advertisements must also include prescribing information in the form of:

- An approved indication or indications for use together with the dosage and method of use;
- A succinct statement of the contraindications, precautions and side effects.

Reminder advertisements

In the absence of local regulations, an abbreviated or "reminder" advertisement is defined as a short advertisement containing no more than a simple statement of indications to designate the therapeutic category of the products.

For reminder advertisements, the requirements in section 1b apply, but the requirements for full advertisements may be omitted, provided that there is a form of words which clearly indicates that further information is available on request.

Mailings

The frequency and volume of mailings of printed material to the healthcare profession should be reasonable. Requests by physicians for their names to be removed from mailing lists for promotional material should be respected, but full mailing lists should be maintained in order to permit provision of

important information concerning adverse reactions, precautions, warnings, etc.

- c)** Information must be accurate, balanced, fair, objective and supported by evidence that is scientifically valid, clinically relevant and up to date. For example:
- the results of a study, which are contradicted or questioned by another scientifically valid and clinically relevant study, may not be cited without qualifications;
 - a study should not be cited or presented in such a way that it could convey an incorrect or misleading impression of the nature, scope, results, implementation or importance of the study;
 - a study performed in vitro or a study based on animal tests should not be cited in such a way that it could give an incorrect or misleading impression of the clinical relevance of the investigation and its application in humans;
 - statements of comparisons between different drugs or alternative treatments should be expressed in such a way as to make the statistical validity and clinical relevance clear; all comparisons must be scientifically appropriate and balanced;
 - the report of such a study should not be cited or abstracted in such a way that the citation or abstract gives an inaccurate or misleading impression of the contents and relevance of the report and the conclusions stated therein.
 - when promotional material relates to published studies, a clear reference to these should be given in the printed material.
- d)** Quotations from medical literature or from personal communications associated with the medical literature shall not change or distort in any way the intended meaning of the author, clinical investigator or the significance of the underlying work or study.

e) Clinical data referenced to unpublished company sources should specify: "Data on file and available upon request." Sufficient information to permit evaluation of referenced data must be made available to recipients of promotional communications either as an integral part of the promotional communication, as a reference to a published report, or upon request. Sources of promotional statements shall be provided by the company within 15 days upon request.

f) Programs shall not disguise or misrepresent their true promotional intent. Examples include market research studies and continuing medical education programs intended to promote a specific product.

g) Particular care should be taken that essential information as to pharmaceutical products' safety, for example, contraindications, precautions, and side effects, is appropriately and consistently communicated, subject to legal, regulatory, and medical practices of each nation. The word "safe" should not be used without qualification.

Substantiated information on serious and unexpected adverse reactions associated with pharmaceutical products should be reported to the appropriate national authority as a priority.

2. Gifts / Promotional Items

a) Items primarily for the benefit of patients may be offered to healthcare professionals if they are not of substantial value (\$150 or less). For example, an anatomical model for use in an examination room primarily involves a patient benefit, whereas a VCR or CD player does not. Items should not be offered on more than an occasional basis, even if each individual item is appropriate. Providing product samples for

patient use in accordance with the Prescription Drug Marketing Act is acceptable.

- b) Items of minimal value (\$25 or less), may be offered if they are associated with a healthcare professional's practice (such as pens, notepads, and "reminder" items with company or product logos).
- c) Items intended for the personal benefit of healthcare professionals (such as music CDs or tickets to a sporting event) should not be offered.
- d) Payments in cash or cash equivalents (such as gift certificates) should not be offered to healthcare professionals either directly or indirectly, except as compensation for bona fide services (as described in parts B.3. and B.4.). Cash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest.
- e) Cultural traditional gifts associated with special social occasions that relate to the healthcare provider such as his/her marriage or sickness or the birth of a child for him/her, family funerals, religious days, etc are acceptable provided that (1) they are limited to flowers or sweets, (2) they do not exceed one gift per social event, and (3) the value of each gift does not exceed US\$ 50.

3. Samples

- a) Samples, clearly identified as such, may be supplied in moderate quantities to the prescribing professions to familiarize them with the products, either spontaneously or upon request.

4. Medical Educational gifts

Medical /pharmacological educational material is acceptable to be sponsored to the health care providers, such as :

- Medical textbooks
- Subscriptions to medical journals

B. CONGRESSES / SYMPOSIA / MEDICAL EDUCATION

- 1. Informational Presentations by or on behalf of a Pharmaceutical Company

Informational presentations and discussions by industry representatives and others speaking on behalf of a company provide valuable scientific and educational benefits. In connection with such presentations or discussions, occasional meals (reasonable entertainment/recreational events) may be offered so long as they:

- a) Are modest as judged by local standards; and
- b) Occur in a venue and manner conducive to informational communication and provide scientific or educational value.

For the workshops taking place over two days, the program should be balanced and a minimum of 6 hours of working session (Medical or scientific or business) is the rule.

Inclusion of a healthcare professional's spouse or other guests is not appropriate.

Offering "take-out" meals or meals to be eaten without a company representative being present (such as "dine & dash" programs) is not appropriate.

Hospitality in terms of Trip coverage (Ticket and Double room) of non-medical accompanying persons to a sponsored congress, should not be covered

2. Third-Party Educational or Professional Meetings

a) Continuing medical education (CME) or other third party scientific and educational conferences or professional meetings can contribute to the improvement of patient care and therefore, financial support from companies is permissible. Since the giving of any subsidy directly to a healthcare professional by a company may be viewed as an inappropriate cash gift, any financial support should be given to the conference's sponsor which, in turn, can use the money to reduce the overall conference registration fee for all attendees. In addition, when companies underwrite medical conferences or meetings other than their own, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines.

b) Companies have an obligation to disclose to participants their direct or indirect sponsorship of their involvement in informational and educational activities. Sponsorship shall be disclosed to attendees prior to educational activities in brief statements in conference materials such as, but not limited to, brochures, syllabi, exhibits, poster sessions, and also in post-meeting publications, clinical reports or supplements to third-party journals.

c) Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-staff * healthcare professionals attending CME or other third-party scientific or educational conferences or professional meetings, either directly to the individuals attending the conference or indirectly to the conference's sponsor (except as set out in section 4 below). Similarly, funding should not be offered to compensate for the time spent by healthcare professionals attending the conference or meeting.

* non academic members (i.e secretaries, technicians, etc.)

d) Financial support for meals or receptions may be provided to the CME sponsors who in turn can provide meals or receptions for all attendees. A Company also may provide meals or receptions directly at such events if it complies with the sponsoring organization's guidelines. In either of the above situations, the meals or receptions should be modest and be conducive to discussion among faculty and attendees, and the amount of time at the meals or receptions should be clearly subordinate to the amount of time spent at the educational activities of the meeting.

e) A conference or meeting shall mean any activity, held at an appropriate location, where: (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentations(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.

3. Consultants

a) It is appropriate for consultants who provide services to be offered reasonable compensation for those services and to be offered reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Compensation and reimbursement that would be inappropriate in other contexts can be acceptable for bona fide consultants in connection with their consulting arrangements. Token consulting or advisory arrangements should not be used to justify compensating healthcare professionals for their time or their travel, lodging, and other out-of-pocket expenses. The following factors support the existence of a bona fide consulting arrangement (not all factors may be relevant to any particular arrangement).

- A written contract specifies the nature of the services to be provided and the basis for payment of those services;
- A legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants; the criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;
- The number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;
- The retaining company maintains records concerning and makes appropriate use of the services provided by consultants;
- The venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting, and any social or entertainment events are clearly subordinate in terms of time and emphasis.
- b) It is not appropriate to pay honoraria or travel or lodging expenses to non-faculty and non-consultant attendees at company-sponsored meetings including attendees who participate in interactive sessions.

4. Speaker Training Meetings

It is appropriate for healthcare professionals who participate in programs intended to recruit and train speakers for company sponsored speaker bureaus to be offered reasonable compensation for their time, considering the value of the type of services provided, and to be offered reimbursement for

reasonable travel, lodging, and meal expenses, when (1) the participants receive extensive training on the company's drug products and on compliance with FDA regulatory requirements for communications about such products, (2) this training will result in the participants providing a valuable service to the company, and (3) the participants meet the criteria for consultants (as discussed in part 3.a. above).

5. Scholarship and Educational Funds

Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution. "Carefully selected educational conferences" are generally defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

6. Independence of Decision Making

No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices.

C. MEDICAL/SALES REPRESENTATIVES

1. Training & Development

Companies are responsible for providing medical representatives with appropriate training that provides sufficient medical and technical knowledge to present information on their company's products in an accurate, responsible and ethical manner.

2. Company Responsibility for Activities

Companies must assume responsibility for misconduct or misrepresentation of product facts by representatives or any other agents in the company.

3. Remuneration

The system of remuneration of representatives should not be such as to influence adversely the proper prescribing of pharmaceutical products by the physician.

D. POST-MARKET INTRODUCTION ACTIVITIES

1. Clinical evaluation and surveillance programs following market introduction should be based on approved protocols and designed to provide new and clinically relevant information to the companies and participating health care providers.

2. Clinical investigators (e.g. for Phase IV studies) have the right to be paid for the studies conducted; funding shall be in direct payments and commensurate with services rendered, and not in shares of a company's stock, deferred payment or incentive payments.

E. DIRECT-TO-CONSUMER COMMUNICATIONS

1. Companies have a shared responsibility with health care providers to communicate directly to patients regarding their prescription drugs, except where expressly prohibited by law. All information shall be accurate, balanced and not misleading.
2. Companies have a shared responsibility with health care providers to help conduct public/patient disease awareness programs to meet growing demands of consumers/patients for more information and to enhance public understanding of disease prevention, signs and symptoms of medical conditions, illnesses, and available treatments. Such activities must adhere to the highest standards of accuracy and fair balance, and support the role of the health care provider.

LEBANON CODE OF PHARMACEUTICAL MARKETING PRACTICES

- The Review Board has 30 days to contact the concerned parties, complete a review of the complaint and issue a recommendation, including corrective action where appropriate. If no reply is submitted from the company alleged to be in violation of the Code, a ruling will be made based solely on material supplied by the complainant.

Level III

- If the complainant is not satisfied with the recommendation or the Review Board is unable to render a judgment within 30 days, the complainant reserves the right to send a letter of complaint addressed to the IFPMA Secretariat in Geneva. The Secretariat of the IFPMA is to forward the complaint under cover letter to the national association representing the company alleged to be in breach of the Code (ABPI, PhRMA, SNIP, Interpharma, VFA, etc.)
- Upon receipt of the complaint, the national association is to forward the complaint under separate cover to the Chief Executive Officer of the company alleged to be in breach of the Code, with a request for immediate response and corrective action, when appropriate.
- In the case where the complaint refers to a company that does not belong to the IFPMA or a national association, the IFPMA will refer the complaint under IFPMA cover to the local regulatory authority.

