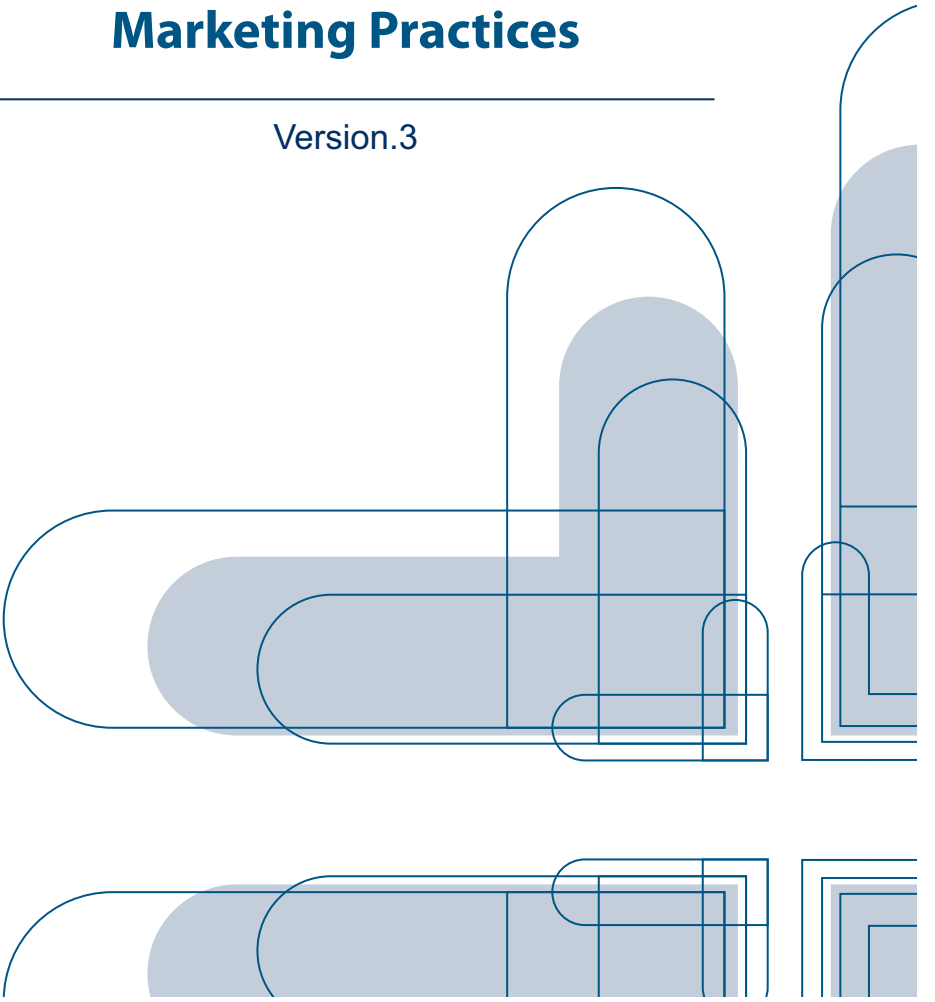
Since 1961

SLCPI

Sri Lanka Chamber of
the Pharmaceutical Industry

Sri Lanka Chamber of the Pharmaceutical Industry Code of Pharmaceutical Marketing Practices

Version.3



SLCPI Guiding Principles on Ethical Conduct and Promotion

Sri Lanka Chamber of the Pharmaceutical Industry (SLCPI) member companies engage in medical and biopharmaceutical industry in-order to benefit patients and support high-quality patient care. Pharmaceutical companies, represented by SLCPI, promote, sell and distribute their products in an ethical manner and in accordance with all the rules and regulations for medicines and healthcare.
The following Guiding Principles set out basic standards to inform the 2012 SLCPI Code of Practice which applies to the conduct of SLCPI Member Companies and their agents. This helps ensure that their interactions with stakeholders are appropriate.

1. The healthcare and well-being of patients are the first priority for pharmaceutical companies.

2. Pharmaceutical companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities.

3. Pharmaceutical companies' interactions with stakeholders must at all times be ethical, appropriate and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence.

4. Pharmaceutical companies are responsible for providing accurate, balanced, and scientifically valid data on products.

5. Promotion must be ethical, accurate, balanced and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use.

6. Pharmaceutical companies will respect the privacy and personal information of patients.

7. Pharmaceutical companies should adhere to both the spirit and the letter of applicable industry codes. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained.

Introduction

(i) The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and marketing new medicines. Ethical promotion helps to ensure that healthcare professionals have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.

(ii) SLCPI and its members are committed to educational and promotional efforts that benefit patients and promotional programs and collaborations that enhance the practice of medicine. SLCPI also seeks to preserve the independence of the decisions taken by healthcare professionals in prescribing medicines to patients. The pharmaceutical industry has an obligation and responsibility to provide accurate information and education about its products to healthcare professionals in order to establish a clear understanding of the appropriate use of prescription medicines. Industry relationships with healthcare professionals must support, and be consistent with, the professional responsibilities healthcare professionals have towards their patients. Pharmaceutical companies must maintain high ethical standards when conducting promotional activities and comply with applicable legal, regulatory and professional requirements. Through the promotion of this Code, SLCPI seeks to ensure and urge that ethical promotional practices are adhered to by all members and non-member companies within the country.

(iii) SLCPI member companies are accountable for addressing and correcting infringements under relevant codes. They should also ensure that internal structures and procedures (including adequate training of employees) are created to ensure responsible and ethical promotional activities. Companies not in membership with SLCPI may elect to be subject to the SLCPI Code and its complaints handling processes.

(iv) The SLCPI is open to receive genuine complaints from any source on any aspect of the SLCPI Code, in accordance with its operating procedures. Where it is determined that there has been a breach of the SLCPI Code, the objective is to correct the matter as rapidly as possible.

The SLCPI Code

1.Objective and Scope

1.1 Objective

The SLCPI Code sets out standards for the ethical promotion of pharmaceutical products to healthcare professionals to ensure that member companies' interactions with healthcare professionals and other stakeholders such as medical institutions are appropriate and perceived as such, being mindful of the well-being of patients'.

1.2 Scope
For the purposes of the SLCPI Code:

• "pharmaceutical product" means all pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) which are intended to be used on the prescription of, or under the supervision of, a healthcare professional, and which are intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body.

• "promotion" means any activity undertaken, organized or sponsored by a member company which is directed at health- care professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all media, including the internet.

• "healthcare professional" means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product.

• "medical institution" means typically an organization that is comprised of healthcare professionals and/or that provides healthcare or conducts healthcare research.

• "member company" means any company that is a member of SLCPI (direct member) or a member of any association that is a member of SLCPI (indirect member). "Company" can refer to national companies and/or the worldwide parent company.

• "member association" means any association that is a member of SLCPI.

2. General Principles

2.1 Basis of Interaction
Member companies' 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.

2.2 Independence of Healthcare Professionals
No financial benefit or benefit-in-kind (including grants, scholarships, subsidies, support, consulting contracts or educational or practice related items) may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on a healthcare professional's prescribing practices.

2.3 Appropriate Use
Promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their properties.

2.4 Sri Lankan Regulations
In all cases, all relevant laws, local regulations and industry code must be observed and both local and foreign based companies have a responsibility to check local requirements, in advance of preparing promotional material or events when marketing in Sri Lanka.

2.5 Transparency of Promotion
Promotion should not be disguised. Clinical assessments, postmarketing surveillance and experience programmes and postauthorization studies must not be disguised promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose. Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by a company should clearly indicate by whom it has been sponsored.

3. Pre-Approval Communications and Off-label Use

No pharmaceutical product shall be promoted for use in Sri Lanka until the requisite approval for marketing for such use has been given.

This provision is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure of information to stockholders and others concerning any pharmaceutical product, as may be required or desirable under law, rule or regulation.

4. Standards of Promotional Information

4.1 Consistency of Product information
It is understood that Sri Lankan laws and regulations usually dictate the format and content of the product information communicated on labeling, packaging, leaflets, data sheets and in all promotional material. Promotion should not be inconsistent with approved product information by the Cosmetics Drugs and Devices Authority of Sri Lanka.

4.2 Accurate and Not Misleading
Promotional information should be clear, legible, accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the pharmaceutical product concerned. Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It should not mislead by distortion, exaggeration, undue emphasis,

omission or in any other way. Every effort should be made to avoid ambiguity. Absolute or all-embracing claims should be used with caution and only with adequate qualification and substantiation. Descriptions such as 'safe' and 'no side effects' should generally be avoided and should always be adequately qualified.

4.3 Substantiation
Promotion should be capable of substantiation either by reference to the approved labeling or by scientific evidence. Such evidence should be made available on request to healthcare professionals. Companies should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.

5. Printed Promotional Material

Where local regulations or codes are in force which define requirements, those take precedence.

5.1 All Printed Promotional Material,

including Advertisements
All printed promotional materials other than those covered in 5.2
below must be legible and include:
- the name of the product (normally the brand name);
- the active ingredients, using approved names where they exist;
- the name and address of the pharmaceutical company or its agent responsible for marketing the product;
- date of production of the advertisement;
- "abbreviated prescribing information" which should include an approved indication or indications for use together with the dosage and method of use; and a succinct statement of the contraindications precautions and side effects.

5.2 Reminder Advertisements
A "reminder" advertisement is defined as a short advertisement containing no more than the name of the product and a simple statement of indications to designate the therapeutic category of the product. For "reminder" advertisements, "abbreviated prescribing information" referred to in 5.1 above may be omitted.

6. Electronic Materials, including Audiovisuals

The same requirements shall apply to electronic promotional materials as apply to printed materials. Specifically, in the case of pharmaceutical product related websites:

- the identity of the pharmaceutical company and of the intended audience should be readily apparent;

- the content should be appropriate for the intended audience;

- the presentation (content, links, etc.) should be appropriate and apparent to the intended audience; and

7. Interactions with Healthcare Professionals

7.1 Events & Meetings

7.1.1 Scientific and Educational Objectives
The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an "Event") for healthcare professionals organized or sponsored by a company should be to inform healthcare professionals about products and/or to provide scientific or educational information.

7.1.2 Events Involving Foreign Travel
No company may organize or sponsor an Event for healthcare professionals (including sponsoring individuals to attend such Event as described in 7.2) that takes place outside of their home country unless it is appropriate and justified to do so from the logistical or security point of view. International scientific congresses and symposia that derive participants from many countries are therefore justified and permitted.

7.1.3 Promotional Information at Events
Promotional information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the Event takes place, or which are registered under different conditions, provided that the following conditions are observed:

- The meeting should be a truly international, scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the Event takes place;

- Promotional material (excluding promotional aids) for a pharmaceutical product not registered in Sri Lanka should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally;

- An explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

7.2 Sponsorship
Member companies may sponsor healthcare professionals to attend Events provided such sponsorship is in accordance with the following requirements:

- The Event complies with the hospitality requirements in this Code as described in 7.5;

- 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 Event; and

- Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend or promote any pharmaceutical product.

7.3 Guests
Companies should not pay any costs associated with individuals accompanying invited healthcare professionals.

7.4 Payments for Speakers and Presenters
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 Event.

7.5 Hospitality

7.5.1 Appropriate Venue
All Events should be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. The additional requirements set forth in Article 7 of this Code also apply accordingly.

7.5.2 Limits of Hospitality
Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the Event and should only be provided:

- to participants of the Event and not their guests; and

- if it is moderate and reasonable as judged by local standards.

7.6 Gifts and Items of Medical Utility

7.6.1 Cash
Payments in cash or cash equivalents (such as gift certificate) must not be offered to healthcare professionals.

7.6.2 Personal Gifts
Gifts for the inappropriate personal benefit of healthcare professionals must not be provided or offered.

7.6.3 Promotional Aids
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.

7.6.4 Items of Medical Utility
Items of medical utility may be offered or provided free of charge provided that such items are of modest value and are beneficial to the provision of medical services and for patient care.

8. Samples

8.1 Samples Permitted
In accordance with local laws and regulations, free samples of a pharmaceutical product may be supplied to healthcare professionals in order to enhance patient care. Samples should not be resold or otherwise misused.

8.2 Control and Accountability
Companies should have adequate systems of control and accountability for samples provided to healthcare professionals including how to look after such samples whilst they are in possession of medical representatives.

9. Company Procedures and Responsibilities

9.1 Procedures
Companies should establish and maintain appropriate procedures to ensure compliance with relevant codes and applicable laws and to review and monitor all of their activities and materials in that regard.

9.2 Training
Companies should also ensure that relevant employees receive training appropriate to their role.

9.3 Responsibilities for Approving Promotional Communications
A designated company employee with sufficient knowledge and appropriate qualifications should be responsible for approving all promotional communications. In the alternative, a senior company employee(s) could be made responsible provided that he or she receives scientific advice on such communications from adequately qualified and trained personnel.

10. Support for Continuing Medical Education

Continuing medical education (CME) helps ensure that healthcare professionals obtain the latest and most accurate information and insights on therapeutic areas and related interventions that are critical to the improvement of patient care and overall enhancement of the healthcare system. The primary purpose of an educational meeting must be the enhancement of medical knowledge and therefore financial support from companies is appropriate.
When companies provide content to CME activities and programs, such material must be fair, balanced and objective, and designed to allow the expression of diverse theories

and recognized opinions. Content must consist of medical, scientific or other information that can contribute to enhancing patient care.
Companies must follow Article 7 of the SLCPI Code where applicable.

11. Operating procedure of the SLCPI Code and the procedure for Code complaints

1. Validation and Referral

When a complaint, alleging a breach of the SLCPI Code, is received by the SLCPI Secretariat, it is first }, referred to the Disciplinary Committee.

The Disciplinary Committee consists of;
The President (Chairman)
Immediate Past President
The Hony. Secretary
If any of the above represent companies against which a complaint is wade they will be replaced by nominees of the Executive Committee of the SLCPI

The Disciplinary Committee will validate the complaint to ensure that:
- it appears to be a genuine matter, submitted in good faith;
- there is sufficient information to enable the complaint to be processed (see paragraph 8.1, below).

A single complaint may cover more than one 'case', i.e. the complaint may refer to several advertisements from different companies and/or for different products. Each 'case' is handled separately by "SLCPI under the main complaint reference. The first action in each case is to identify:
- the company cited in the case.

A summary of each case in the complaint, with a copy of any supporting evidence (e.g. a copy of the advertisement alleged to be in breach of the code) is sent to the Member company or companies, as indicated above, with a copy to the senior management of the company, at local level.

Non-member companies

When a case refers to a company, which does not belong to SLCPI, the case cannot be processed formally. The SLCPI would informally, communicate with the non-member company and draw its attention to the need to comply with the standards set out in the SLCPI Code. The SLCPI would give information on the case to the local regulatory authority.

2. Time Limits

The letter to the Member will indicate the time within which a response must be made on the case under investigation. This is normally 30 calendar days from receipt of the documentation.

3. Response

Where the company acknowledges that it has acted in breach of the Code, information is required on the action that has been taken or will be taken to remedy the matter.
Where the allegations are rejected, the reasons for rejection must be clearly stated and, where appropriate, supporting data (e.g. scientific evidence to support claims which have been questioned) should be provided.
The response(s) from the Member Company/s is/are used in the preparation of the SLCPI decision on the case which is communicated to the complainant, with a copy to the company and respective Company/s

4. Publication of the outcome

When a complaint is upheld and a breach of the Code is determined, information, identifying the company concerned, and the complainant, is immediately made public.

Likewise, information may be made public in cases where the company fails to respond within the agreed time limit.

Status Reports

Status Reports on the SLACPI Code, summarising all complaints received are also published periodically and given wide circulation to government health departments, WHO, the technical press and leading medical journals, and to the Member Companies of SLCPI.
In these reports: :
. Companies found to be in breach of the Code are named and the report describes the nature of the breach, giving also the name of the product, where appropriate;
. Information is given on the cases which have been found to be invalid and those which are outside the scope of the Code, e.g. non-member companies;
. Cases which are rejected - where no breach of the Code is found - are described briefly, but without reference to the product name or company;
. Cumulative statistics are given on the nature and outcome of cases.

Use of the complaint procedure

The SLCPI Code complaint procedure is open to any member of the healthcare professions, a company or the public, acting in good faith within the spirit and intentions of the Code.

1. Submission of Complaints
Complaints must be in writing and include:

2.Source of the complaint
The identity of the complainant, with a full mailing address (e mail and fax number, if possible) for correspondence.

3.Company
For each case in the complaint, the identity of the company which is alleged to be in breach of the Code, and the name of any product or products which are specifically involved.

4. Reference material
For each case, a specific reference to the source of the advertisement/activity which is the subject of the complaint, of printed material or other evidence.

5. Date
The date of the alleged breach of the Code.

All correspondence should be addressed to:

Sri Lanka Chamber of Pharmaceutical Industry
C/o, Ceylon Chamber of Commerce
50, Nawam Mawatha,
Colombo 2
Sri Lanka.
Web site: www.slcpi.org

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