

Cámara Argentina de Especialidades Medicinales (CAEMe)

CODE OF GOOD PHARMACEUTICAL MARKETING PRACTICES AND INTERACTIONS WITH HEALTHCARE PROFESSIONALS

TABLE OF CONTENTS

- 1. PREAMBLE AND ETHICAL, LEGAL AND REGULATORY FRAMEWORK**
- 2. DEFINITIONS**
- 3. PURPOSE AND SCOPE OF THE CODE**
- 4. GUIDING PRINCIPLES**
- 5. GENERAL GUIDELINES FOR INTERACTIONS**
 - 5.1 Transparency of Promotion.
 - 5.2 Organization of Events and Hospitality
 - 5.3 Donations and Grants
 - 5.4 Interactions with Public Officials
 - 5.5 Third Parties
- 6. INTERACTIONS WITH HEALTHCARE PROFESSIONALS**
 - 6.1 Promotion of Medicinal Products
 - 6.2 Promotional Material
 - 6.3 Use of Reference Quotations
 - 6.4 Promotional and other Medical Utility Items
 - 6.5 Visits to Physicians and Pharmacies
 - 6.6 Samples
 - 6.7 Scientific, Educational or Continuing Medical Education Activities
 - 6.8 Services provided by Healthcare Professionals
 - 6.9 Clinical Research
 - 6.10 Market Research
- 7. INTERACTIONS WITH PATIENTS AND PATIENT ORGANIZATIONS**
 - 7.1 Interactions with Patient Organizations
 - 7.2 Patient Support Program
 - 7.3 Interactions with Patients and Caregivers
 - 7.4 Diagnostic Support
- 8. RULES OF APPLICATION**
 - 8.1 Overview
 - 8.2 Queries
 - 8.3 Control of Code Compliance
 - 8.4 Infringements and Penalties
 - 8.5 Implementation Guides and Collaboration Agreements
 - 8.6 Communication and Compilation of Rulings
 - 8.7 Entry into Force

1. PREAMBLE AND ETHICAL, LEGAL AND REGULATORY FRAMEWORK.

The Code of Good Pharmaceutical Marketing Practices and Interactions with Healthcare Professionals constitutes the conduct basis of CAEMe member companies, having as objective the promotion of an ethical and transparent culture while preserving the principles of integrity for the benefit of patients and the general interest of society.

CAEMe and its members are committed to educational and promotional initiatives that benefit patients and promotional programs and collaborations that enhance the practice of medicine. CAEMe also seeks to preserve, within its field of action, the independence of the decisions made by healthcare professionals in prescribing medicines to patients. The pharmaceutical industry has an obligation and a responsibility to provide accurate information about its products to healthcare professionals in order to achieve a clear understanding of the appropriate use of the medicines prescribed.

Industry relationships with healthcare professionals and other healthcare system stakeholders must support, and be consistent with, the professional duties healthcare professionals have towards their patients. Member 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, CAEMe seeks to ensure compliance with good pharmaceutical marketing practices in Argentina

It is a requirement of CAEMe membership that member companies accept the conditions of CAEMe's *Code of Good Pharmaceutical Marketing Practices and Interactions with Healthcare Professionals*, and are subject to local laws and regulations.

They should also ensure that internal structures and procedures (including adequate training of employees) are created to assure that the activities subject-matter of this Code are performed in a responsible and ethical manner and in strict compliance thereof. Companies not in membership with CAEMe may elect to be subject to the CAEMe Code and to its complaint handling procedures

CAEMe is open to receive genuine complaints, regardless of the source, on any aspect of the CAEMe Code, in accordance with its operating procedures. Upon determination of a breach of the CAEMe Code, the objective is to assure the immediate cessation of the infringements.

CAEMe is a non-profit organization representing, among other, major research-based innovative companies of the industry with headquarters or affiliates in Argentina. These companies are committed to observe the ethical standards set out in this Code

For the wording of this Code, CAEMe has taken as reference the IFPMA Code of Practice (International Federation of Pharmaceutical Manufacturers and Associations), the ethics codes developed by the Pharmaceutical Industry in several countries, the ethical criteria for medicinal drug promotion provided by the World Health Organization and current applicable national laws and regulations.

2. DEFINITIONS

For the purposes of this Code:

Caregiver

Person that provides assistance to a patient.

Clinical Trial

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects, and/or to identify any adverse reactions, and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s), whether approved or not by the regulatory authority, with the object of ascertaining its (their) safety and/or efficacy.

Diagnostic support

It comprises support to diagnostic tests provided by member companies.

Events

All meetings, conferences, symposia or any other type of similar activity with scientific, promotional and/or educational nature, including but not limited to meetings of experts, researchers, training meetings or any other meetings organized or sponsored by a member company, directly or indirectly through a third party. The purpose of such events should be to inform healthcare professionals about products and/or to provide and/or develop scientific or educational information related to the practice of medicine.

Healthcare Professional

Notwithstanding provisions contained in the legal rules in force, 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 perform or condition the activities of prescribing, recommending, purchasing, distributing, dispensing or administering a medicinal product.

Medical utility items

Items beneficial to the improvement or provision of medical services and patient care.

Medicinal product

Any pharmaceutical preparation or product used for the prevention, diagnosis and/or treatment of a disease or condition, or to modify physiological systems for the benefit of the receiving individual, designated by a conventional name, whether it is or not a manufacturing brand or trademark, or through the generic name corresponding to its composition and dispensation, with a defined, declared and verifiable quantitative composition, with stable pharmaceutical form and demonstrable therapeutic action.

Member Company

Any company that is a member of CAEMe.

Patient

Any person receiving healthcare, i.e., a person requiring a service in order to maintain, control or recover his/her health status.

Patient Organizations

Non-profit organizations, regardless of their form, mainly composed of patients currently suffering or that have suffered in the past, the same disease and/or their family members or caregivers and, in general, with the purpose of aiding patients and their families to deal with this situation.

Patient Support Program

Any program organized by a member company intended for patients or their caregivers, having received the corresponding prescription of a medicine manufactured or marketed by such member company.

Promotion

Any activity undertaken, organized or sponsored by a member company, directly or indirectly through a third party, exclusively intended for healthcare professionals, to promote the prescription, recommendation, acquisition, distribution, dispensation and administration or consumption of its medicinal products, through any communication media.

Promotional Items

Also called brand reminders or gimmicks, items with no commercial value delivered with promotional purposes.

Promotional Material

Material containing necessary technical and scientific information so that recipients may be informed of the therapeutic properties of the medicinal product.

Public Official

The term “public official” should be construed in a broad sense and it includes:

- Any executive or employee elected or appointed by a government or a government body, governmental agency or state-owned company;
- Any executive or employee elected or appointed by international public organizations, such as United Nations;
- Any person holding an official position, acting for or on behalf of a government or government body, governmental agency or international public organization;
- Politicians and candidates to occupy public offices;
- Any other person considered a public official as per the current sector laws, rules and codes;
- Medical and scientific personnel when working at a hospital, clinic or university, or other similar public or partially public entity.

Sales Representative

The term comprises Medical Sales Representatives and Pharmaceutical Sales Representatives, and any other individual that conducts promotions of medicinal products to healthcare professionals.

3. PURPOSE AND SCOPE OF THE CODE

The CAEMe Code sets out standards for (1) the ethical promotion of medicinal products; and (2) interactions between member companies and healthcare professionals, public officials, patient organizations and other stakeholders with the purpose of assuring that such interactions are appropriate, ethical and transparent, and are perceived as such.

The Code covers all forms of promotion of medicinal products and interactions between member companies and healthcare professionals, in Argentina and abroad.

The Code covers all promotional methods, including but not limited to: press, advertising, direct mail advertising, activities of Sales Representatives, sponsorship of scientific conferences, professional or scientific meetings, Internet, use of audiovisual material such as films, videos, data storage systems and other that may appear in the future, as well as provision of samples and hospitality.

Moreover, the Code covers all forms of interaction between member companies and healthcare professionals, both resulting from research agreements (clinical trials, other studies) and from any other type of agreements (collaboration, consulting, and other services).

The purpose of this Code is neither to restrict the exchange of medical and scientific information during the development stage of a product nor to limit the interactions between member companies and healthcare professionals, but to establish rules of behavior that all member companies commit to comply.

This Code does not regulate the following activities:

- a. Promotion of "over-the-counter" (OTC) products directly intended for the general public. Without prejudice thereto, promotion of OTC products intended for healthcare professionals will be comprised within the scope of this Code.
- b. Prices, discounts and allowances to participants in the commercialization chain, distributors, pharmaceutical wholesalers and authorized pharmacies, that are part of the commercial policy thereof, are not comprised by this Code.
- c. Labels and package inserts of medicinal products.
- d. Supply of non-promotional information by member companies.
- e. Institutional advertising of member companies.
- f. Originals, reprints, literal translations of scientific articles and abstracts published by reputed scientific sources, provided they do not additionally include printed, stamped or electronically linked trademarks or trade names of medicinal products, advertising slogans or other advertising material, whether related or not to such information.

- g. Texts written and prepared by journalists in the course of their professional work in regular editions, supplements, special issues or editions, or other, of newspapers, magazines, television or radio programs, etc., in which information about drug therapies, specific treatments, medicinal products submitted as novelties, scientific studies or papers or references to a medicinal product, lines of research or product launches, press conferences, publications, etc., is presented as a news item, an interview, a debate, an editorial, or another similar format, provided there is no relation between the member company or owner of the trademark or medicinal product and the company responsible for the edition or the author of the information

4. GUIDING PRINCIPLES

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

The Guiding Principles are the following:

- a. Independence of healthcare professionals. No consideration whether in cash or in kind (including scholarships, grants, collaborations, consulting or training contracts, or contracts related to professional practice) may be provided or offered to a healthcare professional in exchange of prescription, recommendation, purchase, dispensation or administration of products or of the commitment to continue doing so. Moreover, nothing may be offered or provided in a manner or on conditions that would imply inappropriate influence on the prescription practices of a healthcare professional.
- b. Member companies will conform to standards of quality, safety and efficacy as determined by regulatory authorities.
- c. Member companies should always act within a legal framework, strictly observing current local laws and regulations.
- d. Member 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 undue influence.
- e. Member companies are responsible for providing accurate, balanced and scientifically valid data on their products.
- f. Promotion must be ethical, accurate, balanced and must not be misleading.
- g. Pharmaceutical companies will respect the privacy and personal information of patients.
- h. Member companies will ensure that all relevant personnel are appropriately trained.

5. GENERAL GUIDELINES FOR INTERACTIONS

5.1. Transparency of Promotion

Any material and/or information related to medicinal products and their uses, sponsored by a company, should clearly indicate that it has been sponsored by such company.

Whenever a member company finances, ensures, or directly or indirectly organizes the publication of promotional material and/or information in newspapers, magazines, radio, television and any other social communication media, it should be expressly stated that such material and/or information is not presented as an independent editorial topic, and the sponsoring company should be included in a visible place.

When member companies organize or participate in events, this fact must be disclosed in all documents regarding the invitation as well as in any published paper, speech or document related to such event.

Member companies will duly document, pursuant to their internal procedures, any transfer of value, they directly or indirectly make to the healthcare system stakeholders. This includes, among other, fees paid for services provided, collaboration given for the organization of scientific and professional events, expenses for hospitality offered due to an event, comprising travel, registration, accommodation and meals expenses, and the provision of scientific or medical publications. Moreover, the duty to document includes all donations or contributions member companies directly or indirectly provide to the healthcare system stakeholders.

5.2. Organization of Events and Hospitality

Member companies may organize, sponsor or support scientific, educational or continuing medical education events intended for the various healthcare system stakeholders, aimed at improving their knowledge on healthcare related issues, enhancement of the quality of life of patients, provision of healthcare services or the sustainability of the health system, among other, and which are related to the areas of interest of the member company.

The purpose and focus of conferences, symposia and other scientific events should be to provide scientific, educational and/or continuing medical education information, and no social and/or recreational activities will be sponsored under any circumstance.

In no case can money be offered to compensate time used by healthcare professionals in attending the event (lost profits). Sponsorship provided to a healthcare professional or any other healthcare system stakeholders should not be conditional upon an obligation to prescribe, recommend, acquire or promote a medicinal product or to obtain an undue advantage for the member company.

Offer or delivery of hospitality independent from a scientific event or with no legitimate business purpose is contrary to the guidelines established in this Code. Hospitality should always be secondary to the main purpose of the event and limited to provision of the necessary means for attendance and participation in such event.

The concept of hospitality includes payment of actual travel, registration, accommodation and meals expenses by member companies, which must be reasonable and limited to the days on which the scientific or professional event is planned to be held. Hospitality cannot be extended beyond a reasonable period after the event. 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. Member companies should avoid using luxurious venues.

Hospitality will not include the sponsorship or organization of entertainment or leisure activities (such as sports events, music events or other).

Hospitality offered by member companies should not be extended to persons other than healthcare professionals.

No payments may be made to healthcare professionals or groups of healthcare professionals, either directly or indirectly, for the rental of meeting rooms unless it is duly evidenced that such rooms are intended for scientific or professional meetings.

Payment of reasonable fees and reimbursement of out-of-pocket expenses related to the provision of the service, including travel for speakers and moderators at such meetings, conferences, symposia and similar scientific or professional events, is acceptable. In the event of hiring foreign healthcare professionals, the market value of the country in which such professional exercises his/her activity will apply.

Member companies cannot organize or sponsor events outside Argentina (international events) unless this makes more sense from a logistics and/or security viewpoint, such as that the majority of invited participants are foreigners and/or multiple countries participate or that a relevant resource or expertise that is the main purpose of the event is located abroad. If international events are organized or sponsored, in addition to this Code, member companies must also observe the specific provisions of the Codes of Practice of the country in which the event is held.

5.3. Donations and Grants

Donations, grants or benefits in cash or in kind to institutions, organizations, associations or foundations related to healthcare areas that provide social or humanitarian assistance services, or conduct research, education or training services, are only allowed if:

- a. They are entities legally created and registered for fiscal purposes;
- b. They are made with the purpose of cooperating with healthcare, research, education/training or social or humanitarian assistance;
- c. They are made based on written applications or acceptances of the entities, clearly describing the program or project and its purpose and benefit, and including how patients will benefit and/or how patient healthcare quality will be improved with such applications. They will indicate how the funds will be used.

- d. They are documented and a copy of such documents is kept by the member company;
- e. They do not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer medicinal products.
- f. The evaluation process and approval of donations or grants will be outside the scope of the commercial, marketing or sales area.

Coverage of recurrent operational expenses related to the daily activities of such entities (such as building rental, employee salaries, utilities, etc.) is not allowed. However, if the application is made by a social or humanitarian assistance institution and there are acknowledged and documented primary needs, this type of donation or contribution may be granted pursuant to the charity or donation contributions program of each member company.

Donations and/or grants to individual healthcare professionals are not allowed.

Educational support to individual healthcare professionals such as rotations in reference healthcare institutions, continuing medical education scholarships and support to research initiated by healthcare professionals may be granted provided they comply with the requirements previously established and payment is made directly to the educational supplier involved

5.4 Interactions with Public Officials

All relations with public officials must comply with applicable rules and regulations, i.e., any rule or provision applicable to Argentine public officials or imposed by their employer.

Member companies should adopt policies and procedures so that all relations with public officials occur in a justified and transparent way, and are duly documented and recorded.

5.5 Third Parties

This Code will be applicable to those third parties executing contracts or any type of agreements with member companies for the promotion, co-promotion and/or licensing of products.

CAEMe member companies should carry out all necessary formalities assuring compliance with the required standards of this code for the relevant type of agreement. In the event of non-compliance by such third parties with the guidelines of this Code pursuant to a promotion, co-promotion and/or licensing agreement of products with a member company, the latter will be responsible for such infringement.

6. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

6.1 Promotion of Medicinal Products

No medicinal product or therapeutic indication may be promoted prior to approval by the competent regulatory authority.

The following will not be considered promotion of medicinal products or therapeutic indications:

- Response by the medical department of a member company, to spontaneous requests originated by an interested healthcare professional related to non-authorized medicinal products or off-label indications, which response expressly states that the medicinal product or therapeutic indication subject-matter of the request has not been licensed in the country.
- Adequate disclosure of scientific data regarding non-authorized drug substances or off-label indications in the country, at scientific events organized by third parties, such as national and international conferences and symposia, provided they have no promotional purpose.
- Public disclosure of information related to non-authorized medicinal products or off-label indications, to shareholders and other interested parties as required by current rules and regulations.
- Information or documents that member companies deliver to doctors in order to be given to patients, with respect to certain medicinal products, which due to the complexity of dosage, route of administration, etc., require the supply of additional information, and provided such information is intended to improve treatment compliance.

All promotional elements of a medicinal product must be consistent with the information contained in the current package insert and with indications approved by competent local authorities.

Information on medicinal products should be accurate and not misleading, precise, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned. Information should be based on an adequate evaluation of scientific evidence and clearly reflect that evidence; and it should not mislead by distortion, undue emphasis, omission or in any other way. Absolute or all-embracing claims should be used with caution and only with adequate qualification and substantiation. Descriptions such as 'safe' or 'no side effects' should be avoided and should always be adequately qualified.

Any information, statement or comparison included in promotional materials should be well-founded. Such foundation (or rationale) should be provided to physicians and all other healthcare professionals on request. Particularly, any comparison conducted between different medicinal products must be scientifically verified. Such rationale need not be provided for statements literally reproducing on-label indications in the current package insert.

6.2 Promotional Material

Any promotional material must comply with the requirements established by the regulatory authorities.

At the time of designing their medicinal products promotion, companies should consider that their first priority is the safety and life of the patients, maintaining a balance between the therapeutic and beneficial characteristics of their products and the information on precautions, contraindications, warnings, drug interactions and side effects, within their promotional campaigns.

Member companies will have in place clear and written policies for the design, review and approval processes of promotional materials and/or activities, as well as a suitable medical department for their endorsement, support and approval.

Each company will be responsible for:

- The scientific endorsement of the content, both of promotional materials and activities related to their medicinal products.
- Procedures for the obtainment, printing, dissemination and appropriate use of scientific references.
- Surveillance, control and consistency of the promotional message with the current prescribing information approved by the regulatory authority.

Promotion should be supported by scientific studies and the qualities of the medicinal product and not by the weaknesses of competitors. Comparison will be acceptable provided it is objective, true and does not contain statements affecting the reputation of third parties. Comparisons must be drawn on analogous or comparable products and should have scientific backing in a publication.

A "brand 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 in accordance with current provisions. The same requirements that apply to promotional printed materials will apply to digital materials, including audiovisuals, videos, films and similar items, and interactive systems.

When the promotional material refers to published studies, such studies should be faithfully reproduced or a clear reference enabling to learn about or find them should be provided. Faithfull reproduction is the reproduction reflecting in full the meaning and content of the original source, without adding or excluding any information that may lead the recipient to mistake or confusion. In this sense, and by way of illustration, when comparing efficacy, safety or other properties of several active substances as an advertising instrument, information such as statistical significance of results may not be omitted nor results from different clinical studies or trials in the same graph or chart be compared without including clarifications, except when the source is a meta-analysis or the result of another work conducted with adequate and acknowledged scientific methodology. Statistics, conclusions or any other datum from several studies conducted pursuant to different methodologies may not be mixed or compared, unless they result from systematic reviews or meta-analysis in which homogeneity criteria are specified. Adaptations that may introduce bias or lead to confusion are not acceptable.

6.3 Use of Reference Quotations

Quotations from medical and scientific literature or from personal communications should accurately reflect the opinion of the author and, if applicable, should mention the product on which the author based its work.

Quotations regarding medicinal products taken from public broadcasts, such as radio or television, and from private events, should not be used without the formal authorization of the lecturer or speaker being the author thereof.

6.4 Promotional and other Medical Utility Items

No gifts, bonuses, benefits in cash or in kind, or incentives may be given, offered or promised to healthcare professionals to induce prescription, recommendation, dispensation, supply, sale, administration or consumption of medicinal products, except those expressly authorized by this Code.

Delivery of the following is not allowed:

- **Cash:** Cash or cash equivalents (such as gift certificates, purchase vouchers or other) should not be offered to healthcare professionals or administrative personnel in any circumstance.
- **Personal Gifts:** Gifts for the personal benefit of healthcare professionals (including, but not limited to, entertainment CDs and/or DVDs, sports or entertainment tickets, electronic items, cultural items, among other) should not be offered to healthcare professionals.
- **Promotional Items:** Delivery of promotional items related to prescription medicinal products is not allowed. However, healthcare professionals may be offered pens and notepads with the name or logo of the member company, in an event organized by such member company, so that they may take notes during such event. Additionally, such items should have a minimal value and their number should be adequate to the purpose of the event.

Promotional Items for OTC products

Delivery of promotional items (also called *merchandising* or *gimmicks*) for the purpose of serving as product brand and/or company logo reminder, is allowed only for OTC products.

There follows the requirements promotional aids must comply with when provided in the course of medical visits and when offered at events attended by healthcare professionals:

- Promotional items provided in the course of medical visits: they must be related to the practice of medicine or pharmacy and/or provide a benefit for patients.
- Promotional items offered at events: they must be related to scientific and/or educational activities attended by healthcare professionals such as items serving as containers of scientific information and/or that may be used by the healthcare professional at the event. Moreover,

promotional aids that can be delivered in the course of medical visits may also be offered at events.

Medical utility items

Member companies may offer or deliver medical utility items provided they have a modest value, they are not items that the healthcare professional should provide for itself or should be provided by the institution in which it exercises its regular professional activity and are beneficial to the improvement of the provision of medical services or patient care.

These items may not be offered more than two times per year per healthcare professional.

Medical utility items may include the name or logo of the member company but not the name of the product, unless the name of the product is essential for the correct use of the item by the patient.

These items should not be used as benefits that may provide an inadequate image, or give the impression of a “preferential” treatment in the use of the products.

Information or educational items to improve patient care

Member companies may provide information or educational items to healthcare professionals for their education or for the education of patients on diseases and their treatments, provided such items are mainly intended for educational purposes.

Information or educational items may include the name or logo of the member company but not of a product, unless the name of the product is essential for the correct use of the item by the patient.

Books and subscriptions may be delivered once per year per healthcare professional, and their value should be reasonable. With respect to other information or educational items, they must have a modest value.

6.5 Visits to Physicians and Pharmacies

Sales representatives should be adequately trained by or on behalf of the member company employing them, and will have sufficient scientific knowledge to present the information on the member company medicinal products in an accurate and responsible manner.

Sales representatives should perform their work in a responsible way, observing the applicable law and ethical rules as well as the provisions of this Code.

Sales representatives should not use any incentive or subterfuge in order to obtain an interview. No payment will be offered or made for the obtainment of an interview.

Both when interviews are arranged and conducted, sales representatives should, from the very outset, take any reasonable steps to ensure they do not generate confusion as to their identity or that of the company they represent.

Sales representatives will comply with rules on pharmacovigilance and adverse event reporting as per the scheme established by each member company.

At each visit, sales representatives will provide to the visited person or will have available for him/her if requested, the current package insert of each of the medicinal products they promote, together with information on the various pharmaceutical forms and doses, prescription and dispensing terms, price information, terms of reimbursement by the National Health System, if applicable, and whenever possible, estimated treatment cost. Promotion of any non-authorized medicinal product or off-label indication is forbidden.

Member companies will take effective actions to ensure that their sales representatives and their personnel related in any way to the preparation or approval of promotional or information material intended for healthcare professionals, are fully conversant and comply at all times with this Code and the applicable regulations on advertising and promotion of medicinal products.

Moreover, they will adopt effective actions and will ensure that interactions between sales representatives and other member company personnel with healthcare professionals comply, at all times, with this Code and with applicable rules.

Pharmaceutical Sales Representatives of member companies who call on pharmacies will comply with the same rules and will observe, in the course of their activity, applicable law on the promotion of medicines as well as ethical rules and the provisions of this Code.

6.6 Samples

In accordance with local laws and regulations, a reasonable number of free samples may be offered to healthcare professionals authorized to prescribe medicinal products, in order that they familiarize themselves with such products and/or initiate therapies.

Member companies should have adequate systems of control and accountability for samples provided to healthcare professionals, including surveillance of such samples whilst they are in possession of sales representatives.

Each sample must bear a statement identifying it as such, by way of illustration “Free Sample - Sale Forbidden”, “Sample with no commercial value” and/or any other term that confirms it is a sample, and not the dosage form licensed for sale. Moreover, the perforated tear-off stub or similar of the medicinal product must be suppressed or cancelled, pursuant to current laws and regulations.

Delivery of samples of medicinal products containing psychotropic or narcotic substances, as defined in the international agreements, or of medicines that may cause dependency or give rise to public health problems for improper use, and of any other medicinal product as determined by regulatory authorities, is forbidden.

Samples distributed through sales representatives will be directly provided to healthcare professionals qualified to prescribe medicinal products or exceptionally to persons authorized to receive them in their name

Samples may not be offered or provided to healthcare professionals as an inducement to or reward for the prescription, administration, recommendation, payment or supply of any medicinal product or service of the member company or to obtain an undue advantage, or for the personal use of the receiving healthcare professional.

6.7 Scientific, Educational or Continuing Medical Education Activities

Member Companies promote Continuing Medical Education (CME) of Healthcare Professionals. In this sense, they may support or perform educational activities that contribute to insure that healthcare professionals obtain the latest and most accurate information and insights for the improvement of patient care and overall enhancement of the healthcare system. The primary purpose of this type of event is the enhancement of medical knowledge of healthcare professionals or other health system stakeholders in furtherance of the provision of optimum care and improvement of patient healthcare.

When member companies provide content to CME activities and programs, such material must refer to on-label uses, be fair, balanced and objective, and designed to allow the expression of diverse recognized opinions. Content must consist of medical, scientific or professional information that may contribute to enhance patient care.

Member companies should establish the necessary procedures to comply with applicable provisions.

6.8 Services provided by Healthcare Professionals

It is allowed to hire healthcare professionals, individually or in groups, for the provision of advisory or consulting services such as lecturer or moderator at meetings, training activities, expert meetings, etc., where such participation involves the payment of remuneration and/or expenses related to the provision of the service.

Criteria for selecting consultants should be directly related to the identified need, and the people in charge of selecting the consultants and/or responsible for the approval of such hiring should have the necessary expertise to assess whether the healthcare professionals meet such criteria.

The number of healthcare professionals providing services should not exceed the number reasonably necessary to attain the anticipated goal.

Agreements covering the lawful provision of this kind of services must comply with the following conditions:

- Clear identification of a legitimate and genuine need for these services in advance of requesting the services and entering into agreements with the prospective consultants.

- Prior to the provision of these services, existence of a written agreement specifying, at least, the nature of the services to be provided and the fees to be paid.
- The hiring of healthcare professionals should not be an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicine.
- The agreement will include a provision pursuant to which the healthcare professional commits to state, in a clear and express manner, that he/she provides services to the company, whenever he/she makes a public statement about an issue that is subject matter of his/her agreement with the company.

The member company requesting the services should keep documentary records of the services provided by consultants, and make use of such services as anticipated.

Fees for services provided by participating professionals should be based on market criteria and in consonance with the time devoted, the work performed and the responsibilities assumed. Each member company should establish a process to assess that agreed fees are in line with the parameters established in this item.

6.9 Clinical Research

All clinical trials and scientific research sponsored or supported by member companies will be conducted with the intent to develop legitimate scientific knowledge that will benefit public health, patients and also advance science and medicine. Member companies are committed to the transparency of industry sponsored clinical trials.

Member companies conduct research activities in which both healthcare professionals and voluntary patients are involved. These activities are performed in accordance with ethics codes, research protocols, medical and scientific standards and national and international rules and regulations.

Research with human beings, including interventional and non-interventional (observational) clinical trials conducted after the licensing of a medicinal product, should neither be the vehicle of concealed promotion nor exercise undue prescribing influence on healthcare professionals.

All pharmacological intervention studies should comply with current rules and regulations. Studies conducted without a scientific purpose and the objective of which is to allow healthcare professionals to acquire experience in the use of a medicinal product or to expand the prescribing habit thereof, are forbidden.

Patient or disease records as well as studies initiated or proposed by researcher-physicians, should not be used for the promotion of medicinal products or to exercise undue recommendation or prescription influence on healthcare professionals.

Design, conduct, funding and publication of sponsored or supported clinical trials will be made outside the Marketing and Sales areas.

6.10 Market Research

Member companies are allowed to conduct market research, whether anonymous or not, to obtain new perceptions or to seek for support elements in business decision-making. Research will comply with the following conditions:

1. The legitimate need for the research should be previously and clearly established, and subsequently, fulfillment of the purpose for which it was contracted will be documented.
2. Market research should not be a mechanism to promote or encourage consumption or prescription of medicines. Surveys with promotional purposes should neither be presented as market research studies nor a remuneration be offered to participants.
3. Research development activities should not be directly conducted by the sales force or marketing personnel of the company.
4. Participants may receive a moderate and reasonable compensation for their participation in line with fair market value and appropriate to time employed, work performed and responsibilities assumed. Payment must be made in cash and must be duly documented.
5. Hiring of healthcare professionals and/or entities through which the research is conducted should be formalized through a written agreement or another equivalent document established with the company sponsoring the study. Such agreements should be approved prior to their implementation, specifying the nature of the services to be provided, their objectives, participation terms, remuneration of professionals, population to be recruited and collection methods.
6. Those conducting the research should be instructed on the mandatory nature of adverse event reporting.
7. Information obtained from such research should be treated in a faithful and lawful way and may only be used for the specific and legitimate purposes for which it was obtained.
8. Behavior of surveyors should be ethical so that no competitor company or product be underestimated or discredited.
9. They must have a written document previously approved by the company, clearly establishing the objectives, methodology, anticipated results and their use.
10. In the event of research studies commissioned or sponsored by more than one company, the analysis of results will be individual, as well as the actions taken based on such information.
11. Member companies should assure that performance of research studies does not constitute an incentive for anti-competitive agreements or practices.

12. Following performance of market research activities, use of the collected information for decision-making support regarding the design of promotional activities is legitimate.
13. Any market research will safeguard the rights of participants and assure the protection and integrity of personal data in compliance with applicable law.
14. This article is not applicable to market research studies consisting of surveys of minor significance.

7. INTERACTIONS WITH PATIENTS AND PATIENT ORGANIZATIONS

7.1 Interactions with Patient Organizations

Scope

The pharmaceutical industry has many common interests with patient organizations. All interactions with patient organizations must be ethical, observe transparency principles and respect their independence.

Statement on Interactions

When working with patient organizations, member companies must ensure that their interactions as well as the nature thereof, are clear and that they comply with the autonomy principle. No company may require that it be the sole funder of the patient organization or any of its programs. Member companies may not use patient organizations to induce the prescription or promotion of medicinal products.

Any interaction with patients as a source of information must comply with the guidelines established by current laws and regulations regarding data privacy and prohibition of direct promotion to consumers of prescription medicines.

Member companies that provide financial support or in-kind contributions to patient organizations must have in place written documents setting out the nature of support, including the activities, funding thereof and evidence of completion.

Member companies may provide several types of support, such as, by way of illustration:

- Donations and grants intended for the primary purpose of the organization;
- Development of joint activities or sponsorship of educational, awareness, early detection and disease prevention activities;
- Scholarships to patient organizations and/or their members to attend events related to their condition. The previous statement may occur provided the primary goal of the event is professional, educational and scientific in nature or that it supports, in some other way, the mission of the patient organization. In all these cases, patient organizations should indicate

from which member company they received a contribution, regardless of the type, for the completion of the relevant activity.

Member companies are not allowed to require any consideration for donations, grants and scholarships provided to patient organizations. In the event of joint activities or sponsorships, consideration for both parties, the patient organization and the member company, should be clearly described in a written document for such purpose.

When member companies hold meetings with patient organizations, companies must ensure that the venue and location are appropriate and conducive to informational communication. In addition, any meals or refreshments provided by a member company must be modest, and in accordance with what is herein established for the organization of events and hospitality.

Hiring of patient organizations and/or some of their representatives for the provision of advisory or consultancy services is allowed, provided there is a clear legitimate need, a fair market value is paid and there is a written agreement between the parties that identifies the purpose, nature and remuneration of the service provided. General guidelines herein established for Services provided by healthcare professionals will be observed even though individuals providing such services are not healthcare professionals.

Use of logotypes and/or institutional materials (printed, digital, web pages, audiovisual, etc.) registered by patient organizations requires the previous consent thereof. Moreover, member companies will not influence the editorial content of patient organizations material to favor their commercial interests.

Member companies commit to establish internal criteria and procedures to approve and follow up the interactions with patient organizations.

7.2 Patient Support Program

Member companies may have patient support programs provided that patients included have received the corresponding prescription of a medicinal product manufactured or marketed by a member company.

Patient support programs may have the following purposes:

- provide information, education on the adequate use of the medication;
- provide access to medication, though, among other, specialists and/or advisors acting in their own behalf or on behalf of the patient.
- support adherence, supplementary tests and/or administration of the medicinal product;
- provide initial or continuing treatment doses, discounts and allowances on the medicinal product.

Within the framework of patient support programs, member companies are not allowed to:

- have as purpose programs for off-label indications not approved by the local regulatory authority;
- provide legal services, encourage, handle, manage, fund or pay for legal actions intending to force access to medicinal products;
- use the program for promotional purposes;
- hire healthcare professionals for the inclusion of patients in patient support programs, nor limit the program, exclusively, to certain healthcare professionals;
- promote programs within patient organizations or to patients;
- take actions against medical autonomy.

Patient support programs will meet the following requirements:

- be appropriately described and documented;
- be intended for patients having previously received the medicinal product prescription from a healthcare professional;
- be managed by an area with no direct commercial objectives;
- any material to be provided to the patient within these programs must have been previously reviewed and approved pursuant to applicable law;
- program diffusion to patients may only be directly made by healthcare professionals;
- any patient entering a support program must provide his/her previous informed consent in accordance with current laws and regulations on personal data protection.

Member companies' sales representatives may inform healthcare professionals on the existence and benefits of patient support programs. Moreover, member companies may have outsourced patient support programs provided the provisions of this chapter are complied with.

Member companies implementing patient support programs, whether directly or through third parties, will observe current pharmacovigilance laws and regulations.

7.3 Interactions with Patients and Caregivers

All interactions with patients as a source of information will comply with the guidelines included in the current laws and regulations on data privacy and prohibition of direct promotion to consumers of prescription medicines.

In the event that a member company needs to interact with patients as a source of information on their experience on the disease, the following requirements will be met:

- Initial contact with patient may not be directly made by a member company, but through a patient organization or healthcare professional;
- No compensation intended to influence patients may be offered or provided. Notwithstanding the previous statement, patients may receive an economic compensation for the provision of a legitimate service to a member company. Compensation will be documented through a written agreement, reasonable as regards market values and in compliance with current laws and regulations. Moreover, payment of costs for patient transportation, accommodation and/or meals related to the service provided, is allowed. Such payment will be made directly by the member company, observing the guidelines established for events and hospitality;
- Payment in kind in exchange of a patient's testimony through the delivery of medical samples or supply of medicinal products, is not allowed;
- The interaction will be appropriately documented prior to the activity, defining the type of testimony to be provided by the patient and the confidentiality clauses to be applied, as well as the obtainment of the express consent and the right to capture, reproduce and use images, when applicable.
- Member companies conducting these practices should have defined procedures in place to secure adequate handling of patient spontaneous requests, assuring observance of guidelines in current laws and regulations on prohibition of direct promotion to consumers and adverse event reporting.

7.4 Diagnostic Support

Member companies may support diagnostic tests conducted in compliance with the following guidelines:

- diagnostic support programs will be exclusively offered to healthcare professionals, and in no event whatsoever to patients;
- they will be prescribed by the healthcare professional to any patient, under no conditions as regards possible prescription of a medicinal product manufactured by the member company;
- there will not be any consideration or personal benefit for the healthcare professional;
- the value of diagnostic tests will be paid by the company directly to the institution conducting or handling the tests, and in no case to the prescribing professional or patient;
- member companies will have no access to and/or information on the results related to the personal data of patients;

- support may not be exclusively limited to certain healthcare professionals.

Selection of the institution conducting the diagnostic tests should be based on objective criteria assuring its suitability and independence. In the exceptional circumstances in which the diagnostic test must be directly conducted by the prescribing physician, compensation will reflect the fair market value, and sponsorship of this service will not be conditioned to the future prescription of a medicinal product.

8. RULES OF APPLICATION

8.1 Overview

Member companies or companies that adhered to the Code commit and undertake to observe the principles contained in this Code in their promotional activities as well as in their interactions with healthcare professionals or with any other person who, in the practice of his/her profession, may perform or determine the activities of prescribing, purchasing, distributing, dispensing or administering a medicine.

Each company should appoint at least one adequately qualified employee or manager, who will be in charge of the internal supervision of Code compliance.

The regulations for the reception, research and decision of complaints received within the framework of the Code of Good Pharmaceutical Marketing Practices and Interactions with Healthcare Professionals (“The Code of Conduct”) of CAEMe explains the basic internal control principles and mechanisms to be observed by all member companies.

Moreover, member companies or companies that adhered to the Code on an individual basis, will be held responsible for possible infringements to the Code committed by third parties acting in their name and behalf, or under their control, or pursuant to a written agreement (e.g.: external sales networks, marketing research firms, travel agencies, advertising agencies, etc.)

8.2 Queries

Member companies subject to this Code may submit queries on the conformity to the Code of a given promotional activity or interaction with healthcare professionals or request clarifications of a more general nature related to the Code. Queries on the content of specific promotional materials are excluded.

Queries should be addressed to the Compliance Commission.

Neither the particular queries submitted nor their outcome may be mentioned in promotional activities or in interactions with healthcare professionals.

Queries of general interest for the whole industry may be published in the form of question-answers, maintaining the anonymity of the company that submitted the query, at the discretion of the Board of Directors.

8.3 Control of Code Compliance

Control of compliance with the rules established in this Code corresponds to the Supervisory Committee and to the Board of Directors.

The composition, appointment and issue of the Regulations of the Supervisory Committee will be defined by the Compliance Commission.

Any reference to the Board of Directors corresponds to the Board of Directors of CAEMe as per its By-Laws.

The Supervisory Committee, the Compliance Commission and the Board of Directors will have the following powers and duties:

Supervisory Committee

The Supervisory Committee will be composed of 3 persons of the Compliance Commission by drawing of lots.

As the body in charge of the active surveillance of Code compliance, the Supervisory Committee will have the following powers and duties:

- a. Cooperate with the Board of Directors in furtherance of the effective application of the rules contained in this Code, whether on its own initiative or on request of any person with legitimate interest.
- b. Suggest possible corrective processes and/or penalties to the Board of Directors, whenever the existence of an alleged Code violation results from its supervisory duties.
- c. Investigate complaints filed pursuant to this Code.
- d. Any other power it may have pursuant to the Code and its Regulations (Exhibit III)

Members of the Supervisory Committee will abstain from participating in cases where conflict of interest exists.

It should be assured that the Supervisory Committee always protects the confidential nature of the information it has access to or it generates in the course of its activity.

Compliance Commission

It will have the following powers:

- a. Preparation of the Supervisory Committee's Regulations and submission thereof to the Board of Directors
- b. Perform advisory, guidance and training tasks with respect to the Code.
- c. Take the necessary actions aimed at investigating if a given promotional activity of one or several member companies complies with the Code.
- d. Make preventive warnings to member companies whenever, in the promotional activities to be performed and pursuant to the data in its possession, there is a risk of infringement.
- e. Issue technical opinions / circular notes on the various topics related to this Code requested by the Ethics Committee, the Board of Directors and/or member companies.
- f. Any other power it may have pursuant to the Code and its Regulations (Exhibit III)

Board of Directors

CAEMe's Board of Directors as defined in its By-Laws, is the ultimate body in charge of the implementation, updating and compliance with this Code.

The Board of Directors will have the following powers and duties:

- a. Approve the Regulations of the Supervisory Committee.
- b. Request periodic reports to the Compliance Commission on the implementation progress of this Code.
- c. Act as last instance jury in cases of investigations of alleged violations to this Code by member companies, ratifying or rectifying the penalties proposed by the Supervisory Committee.
- d. Approve amendments to and/or updating of this Code, based on the powers vested upon it by the General Assembly of CAEMe.

Members of the Board of Directors will abstain from participating in the cases where conflict of interest exists.

In this regard and notwithstanding the request to cease the infringing behavior that may be sent to the member company that committed the alleged infringement, member companies subject to this Code hereby undertake to file their possible complaints against promotional practices or interactions with healthcare professionals of other member companies subject to the provisions of this Code, to the Compliance Commission in first instance and prior to resorting to the Courts of Justice or to the Health Authorities. They also agree to immediately obey and observe the mediation agreements reached and the content of the decisions of the Board of Directors.

Both the complainant and the respondent member companies commit to preserve the confidential nature of the handling of the complaint and its decision, refraining from disclosing any information about it. The Board of Directors will be entitled to disclose the final and non-appealable resolution, pursuant to the regulations to be issued in this respect.

For the effective application of this Code and for the handling and decision of possible complaints to be filed against promotional activities or interactions with healthcare professionals of member companies subject to this Code, the Supervisory Committee and the Board of Directors will abide by the provisions of their respective Regulations.

Failure to cooperate with any of the bodies in charge of supervising compliance with this Code by a member company subject to its provisions will constitute an infringement as established in this Code.

8.4 Infringements and Penalties

Infringements will be classified as minor, moderate or serious in accordance with the following criteria:

- a. Magnitude of the infringement, particularly, its potential risk to the health of patients.
- b. Impact on the scientific or medical community of the practice resulting in the Code infringement.
- c. Unfair competition.
- d. Damage to the image of the pharmaceutical industry.

Following qualification of the infringement as minor, moderate or serious pursuant to the previous criteria, there may be aggravating factors that will be taken into account by the Supervisory Committee and/or by the Board of Directors of CAEMe, at the time of imposing the penalties. Accumulation of aggravating factors may change the initial qualification. Such aggravating factors are the following:

- a. Degree of intentionality.
- b. Failure to comply with prior warnings.
- c. Generalization of the infringement.
- d. Recidivism.
- e. Concurrence of several infringements in the same action or promotional activity.
- f. Economic benefit for the member company resulting from the infringement.

Penalties will be suggested by the Compliance Commission to the Board of Directors, based on their seriousness, within the three levels established by the CAEMe By-Laws, to wit:

- a. Warning
- b. Suspension of member rights for the term of one month up to one year, maintaining the obligations corresponding to its membership class, and
- c. Expulsion

8.5 Implementation Guides and Collaboration Agreements

The Supervisory Committee, with the approval of the Board of Directors, may prepare implementation guides of this Code, in order to provide guidance to member companies regarding adequate compliance with the rules contained in this Code.

8.6 Communication and Compilation of Rulings

The Board of Directors may communicate its decisions through the means it deems appropriate.

8.7 Entry into Force

This updated version of the Code has been approved by the Board of Directors of CAEMe on December 13, 2018. It will be effective as from January 1, 2019, and it supersedes the previous version.