

CODE OF CONDUCT OF THE VENEZUELAN CHAMBER OF MEDICINES (CAVEME)

Harmonized whit the
"FIIM Code of Pharmaceutical Marketing Practices"
effective from January 1, 2007

CHAPTER I INTRODUCTION

- A. The research based pharmaceutical industry is committed to improve the quality of life and health of mankind through research and development of new medicines and the production and commercialization of products of high quality, and reliable according with the highest standards of manufacturing internationally established by the World Health Organization.
- B. In the commercialization of pharmaceutical products in Venezuela, research based pharmaceutical industry applies the same high levels of ethical conduct that are equally applied in all countries, regardless of the level of development of their economic and health systems.
- C. The CAVEME Code of Conduct establishes general principles for ethical conduct on main activities of its members as well as the mechanisms to prevent, correct and eventually sanction the possible infractions that circumstantially any of the members might commit.
- D. The present CAVEME Code of Conduct keeps full concordance with other International Codes of which CAVEME members are integral part, particularly with the International Federation of Pharmaceutical Manufacturers Code (IFPMA), which, by its part, is based upon Ethical Criteria for the Promotion of Medicines established by the World Health Organization in 1988.
- E. The present Code of Conduct is completely harmonized whit the FIIM Code of Pharmaceutical Marketing Practices effective from January 1, 2007 and valid for all countries worldwide in which pharmaceutical investigation companies members of FIIM operate.

CHAPTER II AMBIT OF APPLICATION

- A. The present Code will be applied without exception to all the member companies of CAVEME.

- B. The CAVEME Code does not intend to subrogate, substitute or replace any norm or provision of a legal nature in Venezuela, which in all cases will prevail in the interpretation of any of the provisions of this Code.

CHAPTER III PROMOTION OF MEDICINES

A. Objective and Scope:

1. **Objective:** The CAVEME Code sets out standards for the ethical promotion of pharmaceutical products to healthcare professionals to ensure that member companies' interactions with healthcare professionals are appropriate and perceived as such.
2. **Scope:** For the purposes of the CAVEME Code:
 - a. **"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.
 - b. **"promotion"** means any activity undertaken, organized or sponsored by a member company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all media, including the internet.
 - c. **"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.
 - d. **"member company"** means any company that is a member of CAVEME (direct member) or a member of any association that is a member of CAVEME (indirect member). "Company" can refer to national companies and/or the worldwide parent company.
3. **Exclusions:** The CAVEME Code does not seek to regulate the following activities:
 - a. Promotion of prescription only pharmaceutical products directly to the general public (i.e. direct to consumer advertising).
 - b. Promotion of self-medication products that are provided "over the counter" without prescription.

- c. Pricing or other trade terms for the supply of pharmaceutical products.
- d. The engagement of a healthcare professional to provide genuine consultancy or other genuine services to a member company.
- e. The provision of non-promotional information by member companies.

B. General Principles:

- 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. 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.
- 3. Appropriate Use:** Promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their properties.
- 4. Local Regulations:** In all cases, all relevant laws, local regulations and industry codes must be observed and companies have a responsibility to check local requirements, in advance of preparing promotional material or events in any specific country.
- 5. Transparency of Promotion:** Promotion should not be disguised. Clinical assessments, post-marketing surveillance and experience programmes and post-authorization 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.

C. Pre-Approval Communications and Off-label Use:

No pharmaceutical product shall be promoted for use in a specific country until the requisite approval for marketing for such use has been

given in that country. 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.

D. Standards of Promotional Information:

- 1. Consistency of Product information:** It is understood that national laws and regulations usually dictate the format and content of the product information communicated on labelling, packaging, leaflets, data sheets and in all promotional material. Promotion should not be inconsistent with locally approved product information. Healthcare professionals in developing countries should have access to similar data to those being communicated in developed countries.
- 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.
- 3. Substantiation:** Promotion should be capable of substantiation either by reference to the approved labelling 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. 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.

E. Printed Promotional Material:

- 1. All Printed Promotional Material, including Advertisements:** All printed promotional materials other than those covered in E.2 below must be legible and include:
 - a. the name of the product (normally the brand name);

- b. the active ingredients, using approved names where they exist;
- c. the name and address of the pharmaceutical company or its agent responsible for marketing the product;
- d. date of production of the advertisement;
- e. “abbreviated prescribing information” which should include an approved indication or
- f. indications for use together with the dosage and method of use; and a succinct statement of the contraindications precautions and side effects.

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 E.1 above may be omitted.

F. Electronic Materials, including Audiovisuals:

- 1. The same requirements shall apply to electronic promotional materials as apply to printed materials. Specifically, in the case of pharmaceutical product related websites:
 - a. the identity of the pharmaceutical company and of the intended audience should be readily apparent;
 - b. the content should be appropriate for the intended audience;
 - c. the presentation (content, links, etc.) should be appropriate and apparent to the intended audience; and
 - d. country-specific information should comply with local laws and regulations.

G. Interactions with Healthcare Professionals:

1. Events

- a. **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 member of CAVEME should inform healthcare professionals about products and/or to provide scientific or educational information. The scientific objectives should constitute the principal scope of such meetings, to whose should be

dedicated most of the time available. The invitations and social events should not be incompatible with such objectives.

b. Obligations of Third-Party Events:

- i. All provisions of the Code of Conduct must be respected by the companies of CAVEME, when applicable, during their participation in symposia, congresses and events organized by third parties.
- ii. Member companies of CAVEME that sponsor symposia, congresses and events organized by third parties must declare to the organizers of those events the obligation that they have to obey the Code of Conduct.
- iii. Member companies of CAVEME will refrain from financing events that do not follow the guidelines indicated in this Code of Conduct.
- iv. The existence of the sponsorship of the company or association must be clearly made known before, during and after the meeting and also in its records. Printed, audiovisual material or material with computer support resulting from these meetings must faithfully reflect the presentations and discussions;
- v. If the program is accredited for graduate medical education by a medical or professional organization, the responsibility for the contents of the program will fall on the organization in charge of obtaining the accreditation of the meeting and the assistance of the industry must be made clear;
- vi. No social events or those of another nature must be held in the schedule of the conference, congress or meeting that draw away the attendance of the participants; nor many events of any kind be held outside the schedule of the event that compromise the subsequent attendance thereto, whether on the same day or on the following day.

c. Events Involving Foreign Travel: In principle, all events should be made anywhere within the Venezuelan territory. No company may organize or sponsor an Event for healthcare professionals (including sponsoring individuals to attend such Event as described in G.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.

d. 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:

- i. 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;
- ii. Promotional material (excluding promotional aids) for a pharmaceutical product not registered in the country of the Event 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;
- iii. Promotional material which refers to the prescribing information (indications, warnings etc.,) authorized in a country or countries other than that in which the Event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally; and
- iv. An explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

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

- a. The Event complies with the hospitality requirements in this Code as described in G.5;
- b. Sponsorship to healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees;
- c. No payments are made to compensate healthcare professionals for time spent in attending the Event; and
- d. Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend or promote any pharmaceutical product.

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

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 and will not be

conditioned to any obligation of promoting any particular product at the Event.

5. Hospitality

a. 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. Companies should avoid using renowned or extravagant venues. The additional requirements set forth in Article 7 of this Code also apply accordingly.

b. 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:

- i. to participants of the Event and not their guests; and
- ii. if it is moderate and reasonable as judged by local standards.

c. Guidance from Member Associations: Member associations are encouraged to provide written guidance on the meaning of the terms “moderate”, “modest” and “reasonable”, as used in 7.5.2 and 7.5.4 of this Code, and the meaning of the terms “renowned” and “extravagant” as used in 7.5.1 of this Code. As a general rule, the hospitality provided should not exceed what healthcare professional recipients would normally be prepared to pay for themselves.

d. Entertainment: No stand-alone entertainment or other leisure or social activities should be provided or paid for by member companies. At Events, entertainment of modest nature which is secondary to refreshments and/or meals is allowed.

e. Social Events: Receptions or other social acts held by the companies of CAVEME in the context of the conferences, congresses or events, as well as any social event organized by them, must be serious and in good taste and these activities may not have a value disproportionate to the event, even when they are in accord with the time of dedication. Invitations to these activities must principally distinguish the scientific aspect or reason for the event, and only mention in a secondary manner and with seriousness reception(s) that may offered.

6. Gifts and Items of Medical Utility

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

b. Personal Gifts: Gifts for the personal benefit of healthcare professionals (including, but not limited to, music CDs, DVDs, sporting or entertainment tickets, electronic items) must not be provided or offered.

- c. 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.
- d. 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.
- e. Cultural Courtesy Gifts:** In some countries, if allowed under local law and in accordance with local practice, an inexpensive gift not related to the practice of medicine may be given on an infrequent basis to healthcare professional in acknowledgment of significant national, cultural or religious holidays.
- f. Guidance on Values:**
 - i. The amount for objects of promotion or souvenirs mentioned on G.6.c should not exceed 2 UT (Tax Units)
 - ii. The amount for items of medical utility as mentioned on G.6.d and for cultural courtesy gifts as mentioned on G.6.e should not exceed 10 UT (Tax Units)

H. Samples

- 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.
- 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.

I. Company Procedures and Responsibilities

Companies should establish and maintain appropriate procedures to ensure full compliance with relevant codes and applicable law and to review and monitor all of their promotional activities and materials. A designated company employee, with sufficient knowledge and appropriate scientific or healthcare qualifications should be responsible for approving all promotional communications. Also, a senior company employee could be made responsible, provided that scientific advice is taken.

CHAPTER IV

CLINICAL STUDIES

All clinical research sponsored by the member companies of CAVEME will be developed according to the Guides of Good Clinical Practices, the Declaration of Helsinki, and other Venezuelan, internal and international norms available for this purpose. This implies the existence of:

- A. Ethically defensible and scientifically valid research protocols.
- B. Election of research centers and investigators who are validated and appropriate in regard to the topics to be investigated and the clinical research methodology, aware of their rights and obligations.
- C. Informed consents, which must be complete, real and clear. They must be read, understood and signed as a signal of acceptance by the subject of the study or his legal representative, before any intervention and/or procedure included in the study.
- D. Submission of the protocol to the institutional ethics committees for their approval, before any intervention and/or procedure included in the protocol.
- E. Submission of the protocol, letter of approval of the institutional ethics committees, résumés of the investigators and co-investigators, and letter of commitment of the researchers and the sponsoring company before the health authorities for approval, before any procedure and/or intervention included in the protocol; this in order to comply with the Venezuelan legislation in effect related to research matters.
- F. Monitors, auditors, statisticians, coordinators and medical writers, for the adequate use of the data.
- G. Transparent and clear stipulation of the financial conditions that link the affiliated company with the Research Center and Researchers.
- H. Program on Pharmacovigilance to report events and adverse reactions both from the affiliated company and from the local health authorities and institutional ethics committees.
- I. Absolute respect for the privacy of the subjects of the study.

CHAPTER V

QUALITY ASSURANCE

A. Quality of the medicines offered by the member laboratories of CAVEME

1. It will be assured that all the medicines have full support in regard to scientific information that they have met all the research phases required to be placed on the market and that they have been developed within the maximum standards of quality.
2. The commercialized medicines must offer to the authorities and health professionals complete information based on scientific evidence, which includes the active ingredient, mechanism of action, approved indications, contra-indications, precautions, warnings, reported side effects, posology, risks of pharmacodependence, pharmacological presentations and interactions, without omitting any that appear in the scientific literature or are known by the manufacturers.

B. Oversight of the quality of medicines by the laboratories that are members of CAVEME

1. Each member companies of CAVEME must have an internal program of pharmacovigilance, which allows the control and follow-up of their pharmaceutical products. The policies of these programs must be in accordance with the local legislation and universally accepted standards.
2. It is the responsibility of the member companies of CAVEME to clearly, promptly and immediately notify the health professionals and health authorities about all changes in the information to be prescribed, derived from the internal programs of pharmaceutical oversight.

C. Respect on Doctor's Order (Rx)

1. The member companies of CAVEME will promote the respect of the existing provisions with regard to the obligations of pharmacies to demand the medical prescription when it is in order, and may not suggest or promote the change of that prescription.
2. Educational and promotional materials directed to pharmacies, patients and users must adjust to the norms in effect and must not induce a change in the prescription.
3. No type of promotion will be made under the system of prizes in money or kind. Example: incentives in money or gifts to employees of pharmacy who exert an influence on the change of the prescription.

D. Quality in the production of drugs

1. The member companies of CAVEME will guarantee that the production of medicines meets the Norms of Good Manufacturing Practices demanded by the Law and the universal standards and that the producing plants have permanent programs of improvement and quality control.
2. The member companies of CAVEME that produce generic medicines must manufacture them according to production and quality parameters accepted universally, providing the corresponding bioavailability and bioequivalence proofs.

CHAPTER VI **INTELLECTUAL PROPERTY**

- A. The member companies of CAVEME will promote the strengthening of the legal, administrative and judicial framework of intellectual property and the unrestricted respect of Treaties, Laws and Norms that govern this matter in Venezuela.
- B. The member companies of CAVEME will not produce or commercialize products protected by patents or other intellectual property rights in Venezuela belonging to other companies that are members or not of CAVEME, without the corresponding authorization of the holders of those rights.
- C. The member companies of CAVEME will refrain from using to their own benefit, as a repeated practice, the legal, administrative or judicial weaknesses of the Venezuelan intellectual property system.

CHAPTER VII **MEDICAL VISITORS**

A. Formation and responsibilities

Medical visitors must be adequately formed and have sufficient medical and technical knowledge to present the information on the products of their companies in a precise, responsible and ethical manner. They must inform their company about the contacts maintained with the health professionals and transmit the reports that they receive on the use of products and in particular communications of side effects.

B. Responsibility of the company

All companies will assume the responsibility to correct the infractions of the Code that result from poor behavior or misrepresentation of facts of any medical visitor.

C. Remuneration

The system of remuneration of medical visitors must not be conceived in a mode that may adversely affect the correct prescription of pharmaceutical products by the physician.

CHAPTER VIII **PRINTED PROMOTIONAL MATERIAL**

Printed promotional material must be presented in a legible manner. The scientific base and the presentation of the information of the product must be in conformance with the general principles of this Code and as the case may be with the authorized information of the product.

CHAPTER IX **ENTREPRENEURIAL ETHICS**

A. Public authorities and officials

Under no circumstance may a member companies of CAVEME, its employees or agents of any nature offer, promise or grant a direct or indirect advantage (money or other service or advantage) to the holder of a position, public servant, regulatory agencies, officials that authorize prices, financial and fiscal authorities, authorities of medical attention (including public health officials), environmental authorities, points of frontier crossing (including customs agencies) but also all authorities and judges in general, directly to them or to a third party who represents them, in exchange for that person exercising a function or having undertaken official action in the past or promising to do so in the present or future, violating his official duties; or undertaking any deliberate action that is intended to instigate decisions that would otherwise not have been taken with the same result or at that time.

B. Health professionals and health employees or institutions

Under no circumstance may a member companies of CAVEME, its employees or agents of any nature, offer, promise or grant in the course of commercial transactions for competitive reasons a direct or indirect advantage (money or other services or advantage) to physicians who receive a salary or other employees or workers of hospitals or other medical assistance institutions, insurance companies, medical services, intermediary companies of social security and medical opinion leaders, or to third parties who represent them, in exchange for that person or other person giving unfair preference in procuring commercial goods or services, such as "buying" prescriptions / making arrangements for patients to be changed to products of the company, opinions of expert physicians (favorable), medical publications (favorable).

C. Employees and agents of the member companies of CAVEME

Under no circumstance may the employees or agents of a member companies of CAVEME request, accept a promise from, or accept direct or indirect advantages (money or other services or advantages) or bribes, in commercial transactions for themselves or for a third person in exchange for giving another person unfair preferences in procuring commercial goods or services or other services in opposition to and/or in violation of the rules of the company to which he belongs. This is especially the case with employees who have a responsibility of budget and/or undertaking operations of purchases and all persons who have an influence in decision-making in respect to orders, contracts and prizes in individual cases and in tenders, without excluding any other employee or agent of the company.

D. Prohibited Acts

The Members of CAVEME will consider the following circumstances as indicative that prohibitive acts of corruption have been committed:

1. Violation of the principle of at least two responsible officials in the decisions to purchase;
2. Establish and maintain cash reserves not mentioned in the official accounts;
3. Payment methods outside the normal practices of the company;
4. Pay quotas and/or reimburse costs of services when the service and its compensation are clearly out of reasonable and normal proportion to each other (violation of the principle of equivalence and healthy distance);
5. Pay quotas and/or reimbursements of expenses without written documentation of the service (except in the case of lesser quantities);
6. Reimburse private expenses of employees of the company or expenses not documented as business expenses beyond the limit authorized by the approved regulations;

With respect to transactions with public workers:

1. Lack of written documentation of the transactions (violation of the precept of documentation);
2. Incapacity on the part of the receiver to obtain the approval of the superior or of the office in the name of which the receiver is carrying out official tasks (violation of the precept of transparency);
3. Favors beyond the limits permitted for small gifts to persons who take decisions involving purchases that imply pharmaceutical products in the course of official tasks (violation of the precept of separation).

CHAPTER X
OPERATING PROCEDURES OF THE CODE

The procedure of denunciation of the FIIM Code will be accessible to any member of CAVEME, any member of the health professions, any company that is not a member of CAVEME and the general public, with the sole condition that they act on good faith in the spirit and intentions of the Code.

All denunciations must be channeled through the Executive Direction of CAVEME, which will be in charge of submitting them to the consideration of the Ethics and Discipline Committee of the Chamber after confirmation that a real, serious and well-grounded matter is involved.

The principal objective of the CAVEME Code is to correct as soon as possible any fault confirmed in its operation. The greatest sanction against any company that violates the CAVEME Code will always be adverse publicity against that company. The members of CAVEME, previous notification to the company's Corporate Offices of the violating companies, will be subject to the penalties of public or private warning and of suspension or loss of membership in CAVEME.