

January 2003

Relations between Medical Organizations and
Business Corporations

Code of Ethics
for **parties involved**
in **Continuing Medical Education**



CONSEIL
DE L'ÉDUCATION
MÉDICALE CONTINUE
DU QUÉBEC



Warning

The following organizations have adhered to the *Code of Ethics for parties involved in Continuing Medical Education*, and have undertaken to comply with its provisions:

The Conseil de l'éducation médicale continue du Québec;
The Collège des médecins du Québec;
The Faculty of Medicine, Université de Montréal;
The Faculty of Medicine, Université Laval;
The Faculty of Medicine, Université de Sherbrooke;
The Faculty of Medicine, McGill University;
The Québec Federation of General Practitioners;
The Federation of Medical Specialists of Québec;
The Association des médecins de langue française du Canada;
The Royal College of Physicians and Surgeons of Canada;
The Québec College of Family Physicians;
Canada's Research Based Pharmaceutical Companies (Rx&D).

The Conseil de l'éducation médicale continue du Québec (CEMCQ) and Canada's Research-Based Pharmaceutical Companies (Rx&D) reserve the right to amend the rules of ethics set out in this document at any time, and to modify the complaints processing procedure and the sanctions applicable to individuals and organizations that fail to comply with the Code.

Updates of the Code of Ethics for parties involved in Continuing Medical Education will be available on the CEMCQ and Rx&D websites. Updates will always take precedence over this document.

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Introduction

The explosion of scientific knowledge, technological developments and the necessity for physicians to maintain good relational skills drive a need to organize numerous continuing medical education activities (CME) for both individuals and groups. CME is an essential professional component that helps physicians¹ keep up-to-date and dispense the best possible care.

For many years, business corporations, particularly the member firms of Canada's Research-Based Pharmaceutical Companies (Rx&D), have contributed to CME by helping in a variety of ways to organize activities and encourage the dissemination of information regarding scientific advances in medicine. Educational activities offered in this context, notably to physicians, must help participants acquire, maintain or update their knowledge, skills or attitudes.

Pharmaceutical companies also invest in activities to promote their products as well as consultations with physicians. However, these activities must not be confused with the educational activities in which physicians are invited to participate.

The *Conseil de l'éducation médicale continue du Québec* (CEMCQ) also has certain responsibilities regarding CME. Rx&D and CEMCQ both agree that all the parties involved in CME must ensure that the educational activities they organize or at which they participate are designed first and foremost to help physicians acquire, master, or update their knowledge, skills and attitudes for the purpose of improving the quality of the health care they dispense. They agree that CME activities must be planned, implemented, and administered for the purpose of education, not promotion, and must never be used to promote a particular product or service.

By consolidating the rules that define collaboration between medical agencies and business corporations in the field of CME, Rx&D and CEMCQ wish to ensure the delivery of high-quality, ethical CME activities for the greater good of all concerned.

1. In this code, considerations concerning *physicians* apply to any other participant in a CME activity.

Need to Standardize

Ethical Rules Relating to Continuing Medical Education

In May 1995, the Conseil de l'éducation médicale continue du Québec (CEMCQ) published an Ethical guide to relations between medical organizations and commercial firms concerning continuing medical education. In their Code of Marketing Practices, Canada's Research-Based Pharmaceutical Companies (Rx&D) devote a chapter to rules regarding continuing medical education.

In order to consolidate the rules relating to collaboration between medical organizations and business corporations, Rx&D and CEMCQ have jointly developed and approved the Code of Ethics for parties involved in Continuing Medical Education included in this document.

The Authors

Canada's Research-Based Pharmaceutical Companies

Rx&D is a nation-wide association composed of 62 pharmaceutical research firms employing over 21,000 Canadians. Rx&D member firms have a common goal: to discover medications to be used to improve the health of Canadians. A collection of various-sized firms, Rx&D is part of the global pharmaceutical industry whose members are responsible for more than 90 percent of medications that are commercially available today.

The mission of Rx&D is to improve the quality of life for all Canadians and to contribute to the health care system by encouraging the discovery, development, and accessibility of new medications. To fulfill this mission, Rx&D has set the following objectives:

- Perform and promote health research in Canada;
- Endeavour to give all Canadians full access to innovative medications;
- Increase Canadians' awareness of the pharmaceutical research firms' role in enhancing citizens' quality of life;
- Create awareness of the role of Canada's research-based pharmaceutical companies in developing an effective, comprehensive, and accessible health care system;
- Work in concert with our Canadian health care system partners;
- Promote competitive intellectual property protection and a legislative framework that encourages the discovery and development of new medications in Canada;
- Propose strict standards for the safety and quality of medications;
- Educate health care professionals and consumers on the optimum use of medications.

Conseil de l'éducation médicale continue du Québec

In 1975, at the suggestion of the Collège des médecins du Québec, organizations interested in continuing medical education formed a joint action organization, the *Conseil de l'éducation médicale continue du Québec* (CEMCQ). The CEMCQ is a not-for-profit organization that, over the years, has developed consensus on numerous CME issues. It has also issued a large number of publications.

The mission of the CEMCQ is to promote and improve CME in Québec. Its mandate is:

- among CME organizations, to encourage discussion and promote consensus with a view to harmonizing their actions;
- among CME organizers, to set up and support training activities for CME organizers from faculties of medicine, professional associations and hospitals;
- among participants, to inform physicians in particular of the activities, policies and agreements set up and being developed by the member organizations;
- to encourage research in CME.

The CEMCQ includes one representative from each of the following:

- Collège des médecins du Québec;
- Université de Montréal;
- Université Laval;
- Université de Sherbrooke;
- McGill University;
- Québec Federation of General Practitioners;
- Federation of Medical Specialists of Québec;
- Association des médecins de langue française du Canada;
- Royal College of Physicians and Surgeons of Canada;
- Québec College of Family Physicians;
- Rx&D's Continuing Health Education Working Group.

Definitions

Interaction between business corporations and the physicians may take numerous forms, including product promotion, consulting, and continuing medical education (CME) activities.

The purpose of this code of ethics is to provide a framework for CME activities. The following definitions therefore attempt to clarify the meaning of certain terms and to identify the players involved in CME.

Continuing Medical Education

CONTINUING MEDICAL EDUCATION (CME) Any action designed for, or performed by a physician for the purpose of acquiring, maintaining, or upgrading knowledge, skills, or attitudes to improve the quality of the health care that the physician dispenses to patients. CME may be an individual or group action, based on a need or an interest, being a part of the learning process. (Definition approved by the *Conseil de l'éducation médicale continue du Québec* in 1997)

CME includes, among others, teaching programs designed to update, develop, or increase the knowledge, practices and skills of physicians.

CME ACTIVITY Any educational intervention of varying duration and format that focuses on a given topic. The content must stem from the body of knowledge, skills and attitudes accepted by the medical community as an integral part of medical or clinical science or medical clinical practice.

CME GROUP ACTIVITY Any educational intervention that meets the following pedagogical criteria:

- A needs assessment must be performed;
- The target audience must be clearly identified in the program and the consultation method must be specified; a representative of the target audience must participate in designing and developing the activity program;
- Specific learning objectives must be identified according to pre-established needs. These objectives must be included in the activity program;
- The program must be interactive in format: the audience must be able to take an active part in the proceedings;
- The educational methods outlined and used in the program must enable the objectives to be met; they must also be designed for optimum interaction;

- Participants must evaluate the activity using a specific process; organizers must complete an assessment regarding attainment of the learning objectives.

Interventions that do not satisfy these criteria cannot be considered CME group activities.

A CME group activity must also satisfy the following ethical criteria:

- Organization of the activity must follow a recognized code of ethics;
- Budget estimates must be realistic and ensure adequate sources of funding;
- Social activities associated with the program must not take precedence over or interfere with the scientific content.

CME PROGRAM A series of activities based on a single or various themes and aimed at the same target audience. CME program content stems from the body of knowledge, skills, and attitudes recognized by the medical profession.

ACTIVITY PROGRAM Written document that specifies target audience, activity objectives, content and format of presentations, and identifies the members of the scientific committee, lecturers, and sponsors, if any.

Definitions (continued)

CME Stakeholders

MEDICAL ORGANIZATION Teaching institution, association or group such as a medical faculty, professional association or physicians group within an institution that develops, implements and assumes responsibility for a CME activity or program.

ACCREDITING ORGANIZATION Organization (regional, provincial or national association, faculty of medicine or other teaching institution) that grants CME credits for activities it organizes or that receives applications for granting CME credits for activities organized by other organizations.

ORGANIZER Person or organization responsible for planning, implementing, and administering a CME activity or program on behalf of a medical organization, with the support of a scientific committee.

RESOURCE PERSON Person who assists with a CME activity or program as an expert, speaker, facilitator, or moderator with respect to content or process.

PARTICIPANT Any person, *other than a resource person*, who attends or participates in a CME activity or program for the purpose of acquiring, maintaining, or upgrading knowledge, skills, or attitudes.

Rx&D MEMBER COMPANY Research-based pharmaceutical company that is a member of Rx&D that funds or contributes in some other way to the planning, implementation or administration of a CME activity or program.

PHARMACEUTICAL COMPANY Pharmaceutical company that is not a member of Rx&D and that funds or contributes in some other way to the planning, implementation or administration of a CME activity or program.

BUSINESS CORPORATION Organization that funds or contributes in some other way to a CME activity or program. This organization may be an Rx&D member company, pharmaceutical company, or other business organization.

THIRD-PARTY ORGANIZATION Any private company (communications or other) hired by a medical organization or business corporation to plan, implement, or administer a CME activity or program.

Guidelines

The guidelines governing the various aspects of continuing medical education (CME) focus on the goal of the activities and programs, the stakeholders' objectives and independence, as well as the content of CME activities.

Purpose of Continuing Medical Education Activities and Programs

CME activities and programs are a prime way to ensure the dissemination of knowledge and discoveries in clinical and pharmaceutical research.

The key goal of CME activities and programs must be to enhance participants' knowledge to ensure that they deliver high quality health care to their patients. CME activities and programs are designed to improve knowledge and understanding regarding advances in the fields of research, medical science, and clinical practice. These activities and programs must not be, nor appear to be, in any way geared toward the interests of either the medical organization in charge of the activity, or of the organizers, resource persons, or business corporations.

Content of Activities

The content of CME activities and programs must be balanced and objective, and designed to allow the expression of diverse theories and recognized opinions. Content must consist of medical, scientific or other information that can contribute to enhancing a physician's performance.

The medical organization responsible for the activity or program, in consultation with and with the consent of partners, is responsible for selecting the content, resource persons, and all other materials distributed as part of a CME activity or program.

Partners must agree to ensure that CME activities remain distinct from other types of activities.

Goal of Stakeholders

The goal of CME stakeholders (excluding participants) is to promote and contribute to the planning, implementation, and administration of high quality CME activities and programs. CME activities and programs are planned, implemented or administered by the stakeholders to enable participants to

acquire, maintain, and upgrade knowledge, skills, and attitudes, and are not for promotional or marketing purposes.

Independence of Stakeholders

While planning, implementing, or administering activities and programs, CME stakeholders (excluding participants) must avoid introducing any elements that could threaten their independence or place them in a position of conflict of interest, especially through personal gain, unusually high honoraria, bonuses, or gifts.

Prior to agreeing to participate in a CME activity or program, resource persons must contact the medical organization responsible regarding the existence of a conflict of interest policy and comply with said policy, as required. More specifically, resource persons, at all times exercising proper judgement, must clearly inform the organizer and participants of any affiliations, sponsorships, funding, or other contributions connected in any way to the content of the CME activity or program, or that could affect the objectivity of the activity or program in which they are involved or which involves one or several business corporations.

Resource persons must provide balanced, objective scientific information, demonstrate the advantages and disadvantages of the elements presented, and divulge differing opinions, if any, within the scientific community, while avoiding the promotion of any particular product or service.

Finally, resource persons must avoid taking part in any activities that, under the guise of CME activities or programs are, in reality, used to promote a particular product or service.

Partnership: Purpose, Advantages

Any business corporation or third-party organization developing a continuing medical education (CME) activity or program should make every reasonable effort to do so in partnership with a medical organization. This partnership should be based on common health care values and mutual respect. As much as possible, partners should make use of their expertise and organizational resources when designing and organizing a CME activity or program.

Continuing Medical Education Partnership: A “Win-Win” Solution

For Pharmaceutical Companies

CME activities or programs are a basic instrument used by pharmaceutical companies to disseminate information on discoveries, research, and developments in pharmacotherapy. These corporations feel that it is in their best interest to contribute to the dissemination of new medical knowledge and advances, while ensuring their visibility with medical professionals.

For Medical organizations and Organizers

Since medical organizations and organizers do not always have the human, material, and organizational resources to delivery CME activities or programs, support from pharmaceutical companies is crucial to the delivery of CME activities and programs. It is therefore in their interest to develop relationships with partners who are able to contribute and collaborate in achieving their objectives.

Partnership Goal

Since the primary goal of CME activities and programs is to enhance physicians' performance, the partnership must be based on the educational aspect of a CME activity or program. This must be the motive for and focus of program sponsorship. This requirement applies equally to activities organized by a business corporation that calls upon a third-party agency for delivery.

Operating Procedures

When a partnership exists, resources needed by either partner for planning, implementing and administering a CME activity or program, be they financial, human, organizational or technological resources, must be covered by an agreement between the partners. The partners must use transparent accounting practices that enable each to remain aware of sources of income and expenses.

Social Activities

The social activities associated with CME activities or programs may enhance learning by promoting informal discussion among the participants and experts concerning training or common professional interests. However, when a single activity offers both social and educational segments, the educational portion must take precedence in order for the program to be recognized as a CME activity. Also in this instance, social activities must be reasonable and the cost for all of them, with the exception of meals, must be covered entirely by the participants.

It is incumbent on the partners involved in planning, implementing, and administering CME activities and programs to make joint decisions regarding the relevance and appropriateness of including social activities and which, if any, activities will be provided.

Grants and Honoraria

Resource persons for CME activities and programs may receive grants or honoraria. However, they must not be awarded to other persons, such as spouse or other members of the family of any resource person, physicians participating in CME activities and programs, spouse or other members of the family of these physicians.

Program Evaluation

The CME activity or program evaluation form must include the following question: “Did the activity comply with the *Code of Ethics for parties involved in Continuing Medical Education?*” The form must also show the Web site address at which participants may consult this *Code*.

Participants

Participants in Continuing Medical Education (CME) activities and programs must use critical judgement regarding the presentations and teaching materials made available to them, looking for a balanced and objective content and the discussion of theories or opinions that differ from those of the business corporation supporting the activity or program. They must also be sensitive to any potential conflict of interest on the part of the organizations or resource persons involved in these CME activities and programs.

With the exception of cases covered by accords between the government and medical federations (e.g. compensatory amounts paid by the Régie de l'assurance maladie du Québec to general practitioners taking part in CME activities and programs), participants must refuse any honoraria or refunds – in all or in part – for their travel and accommodation expenses. They must also refuse any gift.

The *Physicians' Code of Ethics* – particularly provisions dealing with integrity, independence, and impartiality – applies to physicians taking part in CME activities and programs.

Implementation

of the Code of Ethics for parties involved in Continuing Medical Education

Adoption of the *Code of Ethics for parties involved in Continuing Medical Education* by Canada's Research-Based Pharmaceutical Companies (Rx&D), the *Conseil de l'éducation médicale continue du Québec* (CEMCQ) and its member organizations implies a commitment from these players to honour the various conditions.

Therefore, any person exposed to a CME activity or program that does not respect the *Code of Ethics for parties involved in Continuing Medical Education* may file a complaint. Any person who is aware of or believes that a violation of this code has occurred may also file a complaint.

Rx&D is conscious of its role in the international pharmaceutical community and is a member of the International Federation of Pharmaceutical Manufacturers Associations, a non-governmental organization with pharmaceutical industry association members from 51 countries. The primary objective of this association is *"to promote and support continuous development throughout the pharmaceutical industry of ethical principles and practices...."*

Rx&D unreservedly supports the Federation's mandate and has adopted a *Code of Marketing Practices* containing rules and principles to which members must adhere and with which they must comply. To apply this Code, Rx&D has created a Marketing Practices Review Committee to receive and examine complaints concerning infractions.

The Collège des médecins du Québec (CMQ), a professional body founded in 1847, regularly accredits medical organizations involved in CME in Quebec. The Bureau of the Collège des médecins du Québec, upon recommendation from its Committee for Admission to practice, grants accreditation. One of the criteria for accreditation is adherence to and compliance with a code of ethics governing relations between medical organizations and business corporations in CME matters.

The CMQ's Continuing Medical Education Committee also has certain responsibilities with respect to CME matters. Among other items, this committee's mandate includes the following: making physicians accountable for their obligation to maintain currency; establishing an inventory of CME resources; developing strategies to maintain currency; and promoting cooperation among organizations responsible for CME.

Implementation of the code of Ethics (continued)

Filing and processing of complaints

Complaints regarding an Rx&D member firm

Any complaint regarding a violation of the *Code of Ethics for parties involved in Continuing Medical Education* by an Rx&D member firm should be addressed in writing to the Rx&D Marketing Practices Review Committee. The Committee will study the complaint and transmit its decision in writing by messenger to all parties involved within 45 days of filing of the complaint.

Complaints regarding a medical organization

Any complaint regarding a violation of the *Code of Ethics for parties involved in Continuing Medical Education* by a medical organization should be addressed in writing to the Continuing Medical Education Committee of the Collège des médecins du Québec. The committee will study the complaint and transmit its decision in writing as soon as possible following filing of the complaint.

Penalties

The following penalties will apply to Rx&D member firms that have been found to be in violation of the *Code of Ethics for parties involved in Continuing Medical Education*:

The following penalties will apply to medical organizations adhering to the *Code of Ethics for parties involved in Continuing Medical Education* that have been found to be in violation of the Code:

1st infraction

Publication of the infraction in the newsletters *Rx&D Update* and *L'Organisateur d'EMC* and a \$5,000 fine;

Sending of a warning letter to the offending medical organization, and publication of the infraction in the newsletters *L'Organisateur d'EMC* and *Rx&D Update*.

2nd infraction

in the same 12-month period

Publication of the infraction in the newsletters *Rx&D Update*, *L'Organisateur d'EMC* and *Le Collège* and a \$10,000 fine;

Sending of a letter of reprimand to the offending medical organization, and publication of the infraction in the newsletters *L'Organisateur d'EMC*, *Le Collège* and *Rx&D Update*.

3rd infraction

in the same 12-month period

Publication of the infraction in the newsletters *Rx&D*, *L'Organisateur d'EMC* and *Le Collège*, a \$15,000 fine and appearance of the Chief Executive Officer before the Rx&D Board of Directors.

A second letter of reprimand will be sent to the offending organization, with a recommendation to the Committee for Admission to practice of the Collège des médecins du Québec to examine the possibility of revoking the certification of the offending medical organization, and publication of the infraction in the newsletters *L'Organisateur d'EMC*, *Le Collège* and *Rx&D Update*.

In all cases, the company found to be in violation will cover publication costs in the newsletters *L'Organisateur d'EMC* and *Le Collège*.

In all cases, the medical organization found to be in violation will cover publication costs in the newsletters *L'Organisateur d'EMC* and *Le Collège*.

Compliance with Rx&D Marketing Practices Review Committee rulings is a condition of membership in Rx&D.

Appeals and arbitration

Complaints regarding an Rx&D member firm

If one of the parties involved disagrees with the decision of the Rx&D Marketing Practices Review Committee, or if this Committee is unable to make a ruling, a request for arbitration may be submitted.

The parties to the arbitration will be: one representative of each of the two parties involved, a representative of the Rx&D Marketing Practices Review Committee and a chair selected by the parties, or failing that, by the chair of the Rx&D Board of Directors.

A written application for arbitration must be presented to the Rx&D Marketing Practices Review Committee within 30 calendar days following receipt of the Committee's ruling.

The decision of the Chair of the arbitration cannot be appealed. Compliance with this decision is a condition of membership in Rx&D.

The parties involved are responsible for their own expenses incurred during arbitration. The party whose appeal is rejected will pay expenses resulting from the appointment and participation of the arbitration chairperson.

Except in the event of appeal or arbitration within the above-mentioned time frames, the decision of the Rx&D Marketing Practices Review Committee is considered final and compliance with this decision is a condition of membership in Rx&D.

Marketing Practices Review Committee
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Website: www.canadapharma.org

Complaints regarding a medical organization

If one of the parties involved disagrees with the decision of the Continuing Medical Education (CME) Committee of the Collège des médecins du Québec (CMQ), or if this Committee is unable to make a ruling, a request for arbitration may be submitted.

In such instances, an Arbitration Board is established consisting of one representative of each of the parties involved, a representative of the CME Committee of the CMQ and a chair selected by the parties, or failing that, by the chair of the CMQ's CME Committee.

A written application for arbitration must be presented to the CMQ's CME Committee within 30 calendar days following receipt of the committee's ruling.

The Arbitration Board's decision is final and must be respected.

The parties involved are responsible for their own expenses incurred during arbitration. The party whose appeal is rejected will pay expenses resulting from the appointment and participation of the Arbitration Board chairperson.

Except in the event of appeal or arbitration within the above-mentioned time frames, the decision of the CMQ's CME Committee is considered final and must be respected.

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Dissemination and implementation

To ensure that parties involved in Continuing Medical Education (CME) adopt the Code of Ethics for parties involved in Continuing Medical Education and that the provisions therein become an integral part of planning, implementing, and administering CME activities and programs, activities for dissemination and implementation of this code must be carried out by related agencies and organizations.

By Canada's Research-Based Pharmaceutical Companies

Canada's Research-Based Pharmaceutical Companies (Rx&D) - as an association - and its member firms agree to disseminate and implement this *Code of ethics for parties involved in Continuing Medical Education* to the parties involved in CME under their jurisdiction, particularly via the following:

- Joint publication of the Code by Rx&D and by the Conseil de l'éducation médicale continue du Québec (CEMCQ);
- Distribution of the Code to Rx&D membership and, within these companies, to persons involved in planning, implementing, and administering marketing activities as well as those involved in planning, implementing, and administering CME activities and programs;
- Publication of articles in *Rx&D Update* regarding the various provisions of the Code;
- Organization of training and information sessions regarding the various provisions of the Code.

By the Conseil de l'éducation médicale continue du Québec

The CEMCQ and medical organizations adhering to the *Code of Ethics for parties involved in Continuing Medical Education* agree to disseminate and implement it among the parties involved in CME under their jurisdiction, particularly via the following:

- Joint publication of the *Code* by Rx&D and the CEMCQ;
- Distribution of the *Code* to CEMCQ members, and, for medical organization members, distribution of the *Code* to organizers acting on their behalf;
- Distribution of the *Code* by the Collège des médecins du Québec to all physicians listed on the Physicians' Roll and to all medical residents;

- Transmission of the *Code* by the Collège des médecins du Québec to the Office des professions du Québec;
- Publication of articles in *L'Organisateur d'EMC* regarding the various provisions of the *Code*;
- Organization of training and information sessions regarding the various provisions of the *Code*.

Acknowledgements

Canada's Research-Based Pharmaceutical Companies (Rx&D), and the Conseil de l'éducation médicale continue du Québec (CEMCQ) wish to thank all those who have contributed to the development of this Code of Ethics:

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Production

Service des affaires publiques et des communications,
Collège des médecins du Québec

Graphic Design

Bronx Communications

Printing

Groupe Illico

Legal Deposit: 1st quarter 2003

Bibliothèque nationale du Québec
National Library of Canada

ISBN 2-922539-04-0 (Conseil de l'éducation médicale continue du Québec)

© Conseil de l'éducation médicale continue du Québec and Canada's
Research Based Pharmaceutical Companies (Rx&D), 2003

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Note: In this publication, the masculine form has been used
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