

# Canada's Research-Based Pharmaceutical Companies



Les compagnies de recherche  
pharmaceutique du Canada

# Code of Ethical Practices

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## Introduction

Canada's Research-Based Pharmaceutical Companies (Rx&D) are aware of and adhere to the ideals of a free and fair society. These ideals include individual freedom, respect for the views of others, the freedom to trade and carry on commerce and the freedom that allows science and medicine to advance their knowledge bases. In recognition of its role in the international pharmaceutical community, Rx&D is a member of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The IFPMA is a non-governmental organization representing pharmaceutical associations in 51 countries around the world. Part of its mission is:

*"To promote and support continuous development, throughout the pharmaceutical industry, of ethical principles and practices voluntarily agreed on...."*

As a member of the IFPMA, Rx&D strongly supports IFPMA's mission and the principles of its Code of Pharmaceutical Marketing Practices.

We urge our Member companies and organizations (Members) to publicly affirm their corporate commitment to honour the principles and ideals that IFPMA has set for our industry.

## Health Care Professional

In this document, the term health care professional means an individual who is currently practicing medicine, nursing, or dispensing medicines in Canada.

## Mission Statement

Members share the mission to improve the health of Canadians through the discovery, development, manufacture, and distribution of innovative prescription medicines. Implicit in this mission are commitments to undertake and promote research, to implement product stewardship, to ensure that health care professionals and patients receive the education and information to use Members' products and services appropriately, and for Members to observe their social responsibilities and role to improve the health and social environments that Canadians enjoy.

## Mission overview

In order to discharge their shared mission, Members commit themselves to conscientious pursuit of responsibilities in the following areas:

- (i) **Research and Development.** Members will conduct and sponsor scientific research in order to develop knowledge that will benefit Canadians, within the ethical framework of Canadian society and scientific associations. This commitment includes:
  - (a) Appropriate input into research design;
  - (b) Unbiased sampling and study design;
  - (c) Proper selection, recruitment and protection of subjects, including patient and non patient subjects;
  - (d) Unbiased interpretation of study data;
  - (e) Appropriate disclosure of study results; and
  - (f) Observance of the above principles in basic, clinical, outcome, and other research.
  
- (ii) **Product Stewardship.** Members accept their accountability for the proper manufacture, distribution, and use of their products. Accountability includes:
  - (a) Maintaining good manufacturing practices;
  - (b) Ensuring appropriate use and reducing risks of misuse;
  - (c) Ensuring safe handling, transportation, and preservation of medications, including storage and disposal;
  - (d) Delivering safe and effective medications; and
  - (e) Ensuring conscientious protection of environmental interests.
  
- (iii) **Provider and Patient Education and Information.** Members accept the obligation to ensure that Canadian health care professionals and patients have access to education and information about the appropriate uses of their products and services. That obligation includes:
  - (a) Providing balanced representation of the benefits and risks of their products;
  - (b) Using non-coercive and non-inducing means and methods of communications;
  - (c) applying this provision of the Code of Conduct (Code) to continuing health education initiatives, clinical evaluation packages (sampling), dealings with medical representatives, market research undertakings, and to whatever other areas it is applicable;
  - (d) Working only within frameworks approved by Health Canada, the Pharmaceutical Advertising Advisory Board (PAAB), and other relevant bodies;
  - (e) Upholding the principles, letter, and spirit of this Code; and
  - (f) Informing health care professionals and patients about appropriate uses of their products and services for individual circumstances.

## 1. GUIDING PRINCIPLES

- The health and well-being of patients and all Canadians is our first priority.
- All interactions with health care professionals are to be conducted in a highly professional, business like, and ethical manner.
- All product information provided to health care professionals must be accurate and fair balanced.
- Clinical trials are developed to further science.
- All Members must adhere to the Code and its intent as a condition of membership.
- No monetary or other consideration is to be given to health care professionals for the purpose of gaining access or influence.
- The purpose of Continuing Health Education (CHE) is to provide balanced and unbiased education to health care professionals.
- The only acceptable form of hospitality for health care professionals are modest meals and/or refreshments.
- Grants, donations and service-oriented items are never to be provided to health care professionals to promote specific prescription medicines.
- Members' sales representatives may not participate in market research, clinical studies, advisory boards and/or consultancy arrangements.
- Advisory boards and consultants are only to be used to gather scientific or commercial guidance.

## 2. ADVERTISING AND INFORMATION DISSEMINATION

**2.1** The prescription medicines that Members have researched, developed, produced and/or marketed are sold mainly in pharmacies and hospitals.

### 2.2 Advertising

**2.2.1** All Members agree to follow the Code of Advertising Acceptance of the Pharmaceutical Advertising Advisory Board (PAAB) and Guidelines for General Advertising, Supplied Advertising Inserts, & Journal Supplements of the Canadian Association of Medical Publishers (CAMP). To the extent the IPRC receives and is guided by information provided regarding a breach of either of these documents, a Member which breaches either of these documents may also be found to be in breach of this Code.

The PAAB is made up of organizations which represent health professionals and institutions, consumers, pharmaceutical manufacturers, the media, advertising firms, and invited non-voting observers. The Therapeutic Products Directorate (TPD) of Health Canada acts as advisor and resource body to the PAAB, while still maintaining its authority under the Food and Drugs Act and Regulations.

The PAAB sets its own policies for the use of its Code of Advertising Acceptance, selects its own Chair and retains a permanent Commissioner of Pharmaceutical Advertising. The Commissioner is responsible to the PAAB for pre-clearance of product advertising, based on the requirements of the PAAB Code.

If the TPD feels that any advertising materials pose a threat to health under the terms of the Food and Drugs Act and Regulations, it can ask that these materials (even if they have been approved by the PAAB) be held back and not used. The PAAB Code describes what actions will be taken should this occur.

Copies of the PAAB Code of Advertising Acceptance can be obtained from the PAAB at 375 Kingston Road, Pickering, Ontario, L1V 1A3 or Web site: [www.paab.ca](http://www.paab.ca)

Copies of CAMP's Guidelines for General Advertising, Supplied Advertising Inserts, & Journal Supplements can be obtained from 1001 Maisonneuve Boulevard, West, Suite 1000, Montreal, Quebec H3A 3E1 or Web site: <http://camponline.org>

## 2.3 New Product Information

**2.3.1** While Members know they are the main source of information about their products, they are also aware that, through the media, news about new prescription medicines may reach the public before this news has reached health care professionals.

Members must take the following steps in order for this not to occur:

**2.3.2** Product information (such as the product monograph or excerpts from it) must be sent to those identified in Section 2.3.3 in a timely manner before the product is launched on the market.

**2.3.3** The information must be sent to all known drug information centres, poison control centres, faculties of medicine and pharmacy across Canada, and national medical associations.

**2.3.4** At any public relations event to announce a new product, a new indication for an existing product or new scientific findings, Members must ensure that all of the facts given to the media are correct and objective.

## 2.4 Signing of Promotional Materials by Medical/Scientific Personnel

Promotional materials are communications whose purpose is to promote a Members' product(s). Such communications must not be signed by personnel who work in medical, regulatory or medical/scientific information services. Nor should they be signed by someone acting on their behalf, regardless of to whom they report. Signed communication from all such personnel should be limited to:

- i) Responses to medical/scientific information requested by the health care professional; and
- ii) Essential, new medical safety information which has not been requested (for example, covering letters for new product monographs and letters that advise on product safety, the withdrawal of a product, new warnings, precautions and contraindications).

## 2.5 Health Care Economic Studies

**2.5.1** Members endorse health care economic studies (or pharmacoeconomic evaluations) that look at the costs and results of alternative therapies. Advertising or promotional campaigns that include the results of such studies must be reviewed and

approved by the PAAB following the same approval system that applies to products or services that contain clinical claims. Claims made as a result of a pharmacoeconomic study or model should be consistent with the Guidelines for Economic Evaluation of Pharmaceuticals: Canada.

## 3. CLINICAL EVALUATION PACKAGES (“SAMPLES”)

### 3.1 General Principle

**3.1.1** Members believe that the timely distribution of Clinical Evaluation Packages (CEPs) to health care professionals, following the rules set out by the Food and Drugs Act and Regulations, provides benefits to both patients and health care professionals.

**3.1.2** CEPs must be dispensed by health care professionals only. Their main use is to begin immediate treatment, as necessary. They can also be used, when appropriate, to determine a patient's clinical response to drug therapy before a full course of therapy is prescribed.

### 3.2 Definition

**3.2.1** For the purpose of this Code, a Clinical Evaluation Package (CEP) is: a package containing a limited quantity of a pharmaceutical product sufficient to evaluate clinical response; distributed to authorized health care professionals free of charge, for patient treatment.

**3.2.2** In addition to the Food and Drugs Act and Regulations governing the manufacture, packaging, storage, and distribution of CEPs, the following regulations also apply:

### 3.2.3 Distribution

- (i) CEPs shall only be given to authorized health care professionals who have filled out a request form for the CEP. The request form must be fully completed by the health care professional before being passed on to authorized company personnel (such as the Members' representative or another designated employee) for signature.
- (ii) An essential part of the CEP service involves providing the health care professional with prescribing information. This information is to be shared with his/her patient.

- (iii) The Member should also provide full prescribing information on the CEP for a minimum of two years following the introduction of a product to the Canadian market. A shorter version of the disclosure may be provided two years after the product is first introduced.
- (iv) All free goods (or CEPs) given to a health care professional as part of an order must be included on the invoice. If no order is made when the free goods are supplied, the goods must be documented on a separate NO CHARGE invoice.
- (v) The number of CEPs provided to a health care professional will not be considered excessive, as long as the health care professional believes that amount is required for the proper evaluation of clinical response.
- (vi) CEPs provided to hospitals must conform to hospital regulations. The hospital's Chief Pharmacist must authorize the acceptance of CEPs before any CEP distribution begins.
- (vii) It is not appropriate to distribute CEPs at conventions.
- (viii) It is unethical, and may be cause for dismissal, for a Member representative to sell, trade or give away CEPs or stock packages to anyone, for any reason, that is not set out in Members policy.

### 3.2.4 Storage

- (i) Rules and safeguards to prevent theft and/or unauthorized distribution of CEPs must be in place at all times.
- (ii) All CEPs must be stored in locked cabinets, storage areas, or rooms which are only accessible to Member representatives or other authorized people.
- (iii) Members must direct their employees to store CEPs in conditions that will maintain their stability, integrity and effectiveness.

### 3.2.5 Disposal

- (i) Members are responsible for ensuring that all excess and/or expired CEPs of their own manufacture are returned to the Members' storehouse or head office.

### 3.2.6 Inventory

- (i) Members must ensure that a complete and accurate inventory of all CEPs held by Member representatives is conducted at least once a year. Inventory will be taken by an auditor assigned by the Member, not by the representative who holds the CEPs.

## 4. EDUCATION FOR HEALTH CARE PROFESSIONALS

### 4.1 Preceptorships

#### 4.1.1 Definition

Health care professionals' preceptorships are educational programs that should facilitate learning and transfer of skills and knowledge from one health care professional to another. These programs allow a local health care professional to spend time with a qualified expert in the field, to gain a better understanding and insight into a therapeutic area or disease state.

#### 4.1.2 General Principle

In order to facilitate the transfer of knowledge and skills among qualified health care professionals, Members may support a preceptorship program. Reimbursement for the expert's travel and accommodation if necessary, and honoraria are acceptable.

Participants in the program may not be reimbursed for any costs or provided honoraria. As an exception to the general principle, a maximum of five health care professionals, per calendar year, per brand, may participate in a preceptorship program in a recognized center of excellence. In this instance, travel and accommodation may be reimbursed.

### 4.2 Speaker Training - new products or indications

#### 4.2.1 Rationale

As new products or new indications are approved by Health Canada, a need may arise to train a small number of key opinion leaders around this information. These health care professionals are an appropriate group of practitioner/prescribers to disseminate this information to their colleagues.

## 4.2.2 Definition

A small group of selected health care professionals trained on new products or new indications for the sole purpose of disseminating this information at subsequent events. These training meetings called “Speaker Training” are designed to train a very select group of key opinion leaders on new products or new indications that meet the requirements of Health Canada regulations.

## 4.2.3 General Principles

Speaker training meetings should involve the selected group of key opinion leaders in the related field to meet at an appropriate venue within Canada. Travel and related expenses including fair and reasonable honoraria may be reimbursed. Appropriate hospitality may be provided (Section 7B); however no other social events (Section 4A.3.4) should be conducted. These participants must have a contract with the member companies to participate in the meeting and deliver subsequent training to health care professionals.

## 4.2.4 Number of Participants/Speaker Training Sessions

The number of speaker training sessions must be limited. Members may only have a limited number of speaker training sessions consistent with the need to train this very select group of key opinion leaders.

Speaker training sessions may not include more than 20 health care professionals per meeting.

## 4.2.5 Special Circumstances

Speaker Training by an International key opinion leader.

- Should the need arise for Canadian key opinion leaders to be trained by an International key opinion leader from a country where the new product or indication is available then Members have the following options:
  - Invite the International key opinion leader to Canada to conduct the training; or
  - Send a maximum of five Canadian key opinion leaders per new product or indication to a recognised centre of

excellence to receive the training. In this instance travel and accommodation may be reimbursed.

## 4A. CONTINUING HEALTH EDUCATION (CHE)

This Section applies to all Members, who are also responsible for the activities of any third party which organizes Continuing Health Education (CHE)<sup>1</sup> events on their behalf.

### 4A.1 Mission Statement

**4A.1.1** The purpose of CHE is to provide and promote high quality health education programs for health care professionals, in partnership with groups that provide accredited CHE programs, such as:

- University faculties of health sciences;
- Health care associations; and
- Other Canadian accrediting CHE bodies.

The partnerships should be based on shared health values and mutual respect.

CHE programs serve to enhance knowledge and understanding of advances in health research, health sciences and clinical practice so that health care professionals can, in turn, provide superior health care to patients. The benefits of this impact all Canadians.

**4A.1.2** When embarking on such partnerships, Members will:

- Support, where possible, the principles and practices of CHE programs established by professional bodies such as:
  - The Royal College of Physicians and Surgeons;
  - The College of Family Physicians of Canada;
  - The Federation of General Practitioners of Québec (FMOQ);
  - The Federation of Medical Specialists of Québec (FMSQ);

<sup>1</sup>The phrase Continuing Health Education is intended to apply to all health care professionals, so that the word “health” may be replaced by “medical”, “nursing”, “dental”, “pharmacy” etc. depending on the audience.

- The Québec Council on Continuing Medical Education (CEMCQ);
- The Canadian Council on Continuing Education in Pharmacy (CCCEP); and
- Other Canadian accrediting bodies.
- Provide a balanced program of current scientific, biomedical, or other relevant information that adds to knowledge and enhances best practices in the health care professions.
- Contribute organizational expertise and resources.

## 4A.2 Definition of Continuing Health Education

Members are committed to separating CHE from other types of activities. CHE programs must be accredited or they must meet the principles for CHE described in Section 4A.2.3. Only those programs that meet and follow these criteria are considered CHE events under this Code.

**4A.2.1** CHE consists of those educational programs which serve to maintain, develop, or increase the knowledge, skills and competence which a health care professional uses to provide care to patients, or service to the professions.

**4A.2.2** The content of CHE programs must reflect that body of knowledge and skills which is accepted by the professions as constituting the basic health sciences, clinical sciences and clinical practice of the professions.

**4A.2.3** A CHE program must adhere to the following principles of adult learning:

- A learning needs assessment must be conducted;
- A member of the target audience must help design and develop the program;
- Clear learning objectives must be identified based on the needs assessment, and the objectives must be reflected in the program;
- The program must be interactive; and
- A final evaluation which outlines how the learning objectives were achieved, must be conducted.

If these five principles are not met, the program cannot be promoted or designated as “educational.”

## 4A.3 General Principle

Symposia, congresses and other CHE programs are vital ways for Members to dispense knowledge, and for health care professionals to share their experiences with each other. The main goal of such meetings must be the enhanced well-being of all Canadians, through better health care. For this reason, the educational program must be the main focus of, and reason for, sponsoring or participating in an event.

These requirements apply to all types of CHE programs, including events organized by the Member and events organized through a third party.

**4A.3.1** The program’s scientific content (as described in Section 4A.2.2) must be developed by consensus among the Member(s) and their CHE partner(s).

**4A.3.2** The kinds of resources needed to organize the program (i.e. financial, people, expertise, technology) must also be agreed upon by the Member(s) and their CHE partner(s). The partners shall adopt an “open book” style of accounting; each partner has the right to know the financial, personnel and technological resources spent on, or donated to, a CHE program.

**4A.3.3** In order to avoid timing conflicts or duplication of programs, Members and/or the program partner should inform local scientific and/or professional bodies of the dates and times of a CHE program.

**4A.3.4** Member companies should not be involved in the development of, or payment for social functions conducted in conjunction with any CHE event.

**4A.3.5** Grants and honoraria may be provided to health care professionals who speak at or moderate CHE programs. Such grants and/or honoraria do not apply to other health care professionals attending the program.

**4A.3.6** Representatives of Members who attend a CHE program must follow the standards and guidelines outlined in the following sections of this Code:

- Section 1 - General Principles;
- Section 3 - Clinical Evaluation Packages; and
- Section 8 - Representatives of Pharmaceutical Companies.

**4A.3.7** For events that have not been accredited, or which do not meet the principles of adult learning described in Section 4A.2.3, but which involve the presenting of medical/scientific information, organizers must conform to the spirit of Section 4 and, in particular, must adhere to Sections 4A.3.4 and 4A.3.5.

**4A.3.8** The CHE programs organized by Members or through a third party are designed for health care professionals and invitations are to be extended only to health care professionals. These programs must not be offered to the spouses/companions or family members of health care professionals unless they are invited health care professionals as well. It is recognized that health care professionals may wish to travel with their spouses/companions or family members. Should they choose to do so, the planning and costs of the travel, accommodation, and meals and beverages of the spouses/companions or family members are the responsibility of the health care professionals. Members must not in any way offer support or facilitate the travel and accommodation arrangements of spouses/companions or family members of health care professionals, or extend hospitality to them, unless they are invited health care professionals as well.

## 4B. SPONSORSHIP TO INTERNATIONAL CONTINUING HEALTH EDUCATION EVENTS, SCIENTIFIC SYMPOSIA, CONGRESSES

### 4B.1 Definition - International CHE events

International CHE Events are defined as events that have been approved, endorsed, or sponsored by learned societies, and professional associations or bodies.

International CHE Events must take place outside of Canada in order for this Section to apply; when held in Canada, Section 4A applies.

### 4B.2 General Principle

In addition to their commitment to provide and promote, high quality health education programs for health care professionals in Canada, Members have a role to play in ensuring that Canadian physicians are educated and kept informed on developments in health research, health sciences, and clinical practice at the international level. To that end, they may receive and consider requests from individual physicians, specialty societies, and/or academic institutions for financial assistance to participate in international CHE events. In addressing this situation, both the supporting Member and the recipient(s) of the financial support should proceed on the understanding that the ultimate objective in exposing Canadian health care professionals to international CHE events is to improve health care for Canadians.

**4B.3** In considering such requests, Members must comply with the following requirements:

- The request must be received in writing, and must include all details of the program, as well as the specifics of the educational program(s) to be delivered by the participant(s) on their return to Canada.
- The Member providing the support must respond to the request in writing, outlining the conditions/requirements underpinning the financial support.
- The Member must require the individual to advise whether or not he/she has requested support from more than one Member company to attend the same event.
- The individual(s)/organization(s) requesting the support must be required to share with Canadians the benefit of knowledge gained through (a) the submission of a report or paper to the supporting company, and (b) through a written report to the specialty society/academic institution or (c) a verbal presentation to health care professionals. Such papers and/or presentations must include a statement by the author/presenter acknowledging that financial support to attend the international CHE event was received, and such acknowledgement must identify the company from which the support was received.

- Members may provide financial support for a maximum of ten (10) individuals to any one international CHE event. Notwithstanding the provisions in Section 7B.1.3, a member company may extend hospitality to all their duly sponsored health care professionals to international CHE event. For hospitality, please refer to sections 7B.1.4 and section 7B.1.5.

### 5. CONVENTION/CLINIC DISPLAYS

#### 5.1 General Principle

Convention/Clinic displays allow for enhanced interaction between health care professionals and the pharmaceutical industry. The main purpose of such displays must be the presentation of accurate information about the product(s) on display.

**5.1.1** At least one qualified representative of the Member must be on site at all times after the convention/clinic display is set up, and until it is dismantled.

**5.1.2** Where no exhibit space is available, a Member may not make a contribution towards a convention display.

**5.1.3** Promotional and educational material available at the display shall not present information or claims that differ in any way from the official product monograph(s).

**5.1.4** Reprints of scientific and medical papers may be distributed at the display, provided they are reprinted verbatim, and are not presented in a manner which differs in any way from the official product monograph(s).

**5.1.5** Giving out CEPs at convention/clinic displays is not permitted.

**5.1.6** Member representatives who are looking after a display must abide by all standards of behaviour for pharmaceutical representatives, as set out in this Code.

**5.1.7** The fee a Member pays for exhibit space must not include additional donations to the association holding the convention. Additional donations must be reported as such.

**5.1.8** If a Member sponsors a public relations event associated with a convention, the cost of that event must not exceed the cost of a single exhibit.

**5.1.9** Sponsorship of Member-specific social functions is not permitted.

**5.1.10** Members must not pay for or make a donation to displays set up on an ongoing basis at clinics/hospitals.

### 6. DONATIONS OR FINANCIAL SUPPORT

#### 6.1 General Principle

As a demonstration of good corporate citizenship, Members recognize their responsibility to support worthwhile activities both within and outside their communities.

A rationale and clear objective consistent with the Guiding Principles of the Code of Conduct should accompany all requests for financial support. When accepting a request Members should clearly indicate in writing to the requesting party what the Member is supporting.

**6.1.1** Donations, including donations in kind, may be provided to organizations involved in promoting artistic, charitable, cultural, community, educational, humanitarian, health, philanthropic, and sporting activities. Members must ensure that such support is not undertaken for product promotional reasons, and is not directed to product promotion purposes. Acknowledgement by the recipient organization of such support must be restricted to an appropriate statement of support, and the corporate name and logo of the donating Member.

**6.1.2** Where Members provide financial support to a charity and/or non-profit organization through such avenues as the purchase of a table or tables at a dinner or other social event, or through the purchase of a foursome or foursomes at a golf tournament, or similar activity, individuals invited to sit at the corporate table(s), or to play golf as part of the foursomes, should not be health care professionals.

**6.1.3** Members must never provide a donation, directly or indirectly, in order to have access to a health care professional.

#### 6.2 Access Fees

Under no circumstances shall a Member company pay a “clinic room rental fee”, “clean-up fee” or any other similar type “fee” that can reasonably be construed as a direct or indirect payment in order to gain access to a HCP.

## 7A. GIFTS

### 7A.1 General Principle

Members recognize their responsibility to ensure the appropriateness and professionalism of their interactions with health care professionals.

**7A.1.2** Members must not offer to any health care professional, or to any member of a health care professional's clinical/administrative staff, any gift - in cash or in kind, or any promotional aid, prize, reward, or any other item which is intended for personal/family benefit, or pecuniary advantage.

## 7B. HOSPITALITY

### 7B.1 Definition

In order to facilitate greater interaction around our business, Members may provide modest meals/refreshments to health care professionals. The primary objective of the hospitality should be to create the appropriate venue and interaction. Hospitality should not be utilized as the primary access to meet with health care professionals, but as an opportunity to expand the business discussions.

Members are prohibited from reimbursing employees for activities such as but not limited to golf, hockey, theatre and the spa. Member employees should not partake in such activities with health care professionals outside of the limited exceptions as described in Section 6.1.1 or as part of congresses/symposia that are incidental to these events and which are not organized by Member companies.

**7B.1.2** During interactions with health care professionals, Members may only provide refreshments/meals to participants that are modest in content and cost. In all instances, the provision of refreshments/meals must be clearly incidental. No other form of hospitality or entertainment is to be provided.

**7B.1.3** A maximum of five (5) health care professionals is permitted, per interaction. Although there may be more than one Member representative in attendance, the number of healthcare professionals cannot be increased to result in larger groupings.

**7B.1.4** Under no circumstances can refreshments/meals be extended to spouses/companions of health care professionals unless the spouse/companion is himself/ herself a health care professional.

**7B.1.5** As the interpretation of modest can clearly vary across the country depending on city or province, the onus is on Members to ensure that the venue is not excessive and/or "five star". Acceptable examples would be a meal/refreshment at any of the national "mid-range" hotel chains (e.g., Marriott, Hyatt, Sheraton) or similar types of local venues.

**7B.1.6** While hospitality in the form of modest refreshments/meals may be offered during interactions, providing tickets, vouchers, or defraying the costs of this or any other event is not permitted.

## 8. REPRESENTATIVES OF PHARMACEUTICAL COMPANIES

### 8.1 General Principle

**8.1.1** Representatives of pharmaceutical companies represent both their company and the pharmaceutical industry as a whole in the eyes of health care professionals. They are the main point of contact between the pharmaceutical industry and other partners in Canada's health care sector.

**8.1.2** For this reason, the industry establishes and maintains high standards in the recruitment and selection (within the principles of employment equity) of representatives, to ensure that well-qualified people are hired. Ideally, Member representatives should be graduates of universities or community colleges or hold a designation in the health care field.

### 8.2 Standards for Employment and Training

**8.2.1** When a representative is hired, supervised training must be provided to enable the person to become familiar with and carry out their responsibilities. This training will require new employees to acquire both technical and scientific information on Member products, as well as knowledge of the ethical principles and standards of conduct set out in this Code.

**8.2.2** From time to time, Members shall conduct refresher courses for representatives. Members should also encourage all representatives to take courses of study and self-improvement.

**8.2.3** To ensure professional standards for the industry, Member representatives must pass the accreditation course offered by the Council for Continuing Pharmaceutical Education (CCPE) within two years of their employment.

**8.2.4** Member representatives must display the highest professional and ethical standards at all times. This must be reflected in both their conduct and appearance. Representatives are expected to understand and abide by established codes of conduct and courtesy in physicians' offices, clinics, hospitals, retail pharmacies and wherever they may appear in a professional capacity.

**8.2.5** Representatives must provide full and factual information on products, without misrepresentation or exaggeration. Representatives' statements must be accurate and complete; they should not be misleading, either directly or by implication. Their assertions must be scientific and should not vary in any way from the official product monograph and current Canadian medical thinking.

**8.2.6** Member management shall work with representatives on a regular basis to ensure appropriate information exchange occurs as stated in Section 8.2.5.

**8.2.7** Under no circumstances shall Member representatives pay a fee in order to gain access to a health care professional.

## 9. POST REGISTRATION CLINICAL STUDIES

### 9.1 Definition

A post registration clinical study (for the purposes of this Section 9, "study" or "studies") is any study within the approved indications that is conducted after Health Canada's Notice of Compliance has been issued for a drug or product.

A study with the underlying purpose to familiarize HCPs and/or patients with the use of a drug or encourage its prescription, often referred to as "seeding" or "experience" trials, is not an acceptable study.

### 9.2. General Principle

**9.2.1** The main purpose of a study will be to answer a scientific question which requires obtaining and evaluating data on safety and/or efficacy, effectiveness, cost effectiveness, quality of life, functional or other socio-economic factors that have to do with clinical use of the medicine.

**9.2.2** Studies must provide a scientific framework for investigation of the medicine in broader or special populations.

**9.2.3** All studies must have a clearly defined objective which is amenable to scientific review and testing. Duplication or redundancies in studies must be medically and ethically justifiable.

**9.2.4** The company must ensure that studies are designed/approved and administered by qualified people in the medical/scientific department, using the same kinds of methodology (i.e. the planning, protocol development, monitoring and data interpretation) that apply to pre-marketing trials.

As the post-registration clinical study may include the dissemination of devices or diagnostic equipment (including, without limitation, blood pressure monitors and glucose meters) for use by the physician or the subject as part of the clinical study, it is the company's responsibility to ensure that this material is appropriately distributed prior to the study and collected subsequent to the study, by the medical/scientific department. Member companies must maintain a record of dissemination to health care professionals and use reasonable methods to retrieve this equipment from the health care professionals upon the completion of the study.

Other company representatives' role in the process must be limited to the distribution and collection of materials pertinent to the study, on behalf of the medical/scientific department.

**9.2.5** Studies must be carried out in accordance with the *Food and Drugs Act* and *Food and Drug Regulations*, other applicable federal and provincial legislation, guidelines issued by Health Canada, and applicable privacy legislation. Such studies are to be conducted in accordance with the *Food and Drugs Act* and *Food and Drug Regulations* (including the principles of Good Clinical Practice described therein), the International Conference on Harmonization-Good Clinical Practice: Consolidated Guideline, and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.

**9.2.6** Studies must be carried out using a written protocol that will provide answers to specific research questions. All studies must be consistent with good clinical practice. The protocol must be designed to ensure scientifically meaningful results, and should contain details about the following:

- (a) Study background/scientific rationale;
- (b) Study objective;
- (c) Study design;

- (d) Study population;
- (e) Adverse event reporting;
- (f) Sample size based on primary and/or secondary endpoint;
- (g) Description of measures to minimize bias (such as randomization or blinding);
- (h) Study methodology;
- (i) Duration of subject participation and study duration;
- (j) Data collection method;
- (k) Predefined statistical plan consistent with the objectives; and
- (l) Appropriate external reporting of results (e.g. in a peer reviewed journal or on a clinical trial website).

**9.2.7** Researchers must collect data according to the protocol and keep the research results on file with the Member as required by applicable law and/or regulations.

**9.2.8** After the data is collected but before the study is published, the researchers and medical/scientific department of the Member must jointly review the scientific evaluations of data.

**9.2.9** Researchers' pay must reflect costs incurred in conducting the study, such as professional fees, salaries of study staff, and laboratory tests. Payment may be in the form of a monetary grant, travel to attend scientific and medical meetings, and/or equipment, provided the latter is needed for and relevant to the study. Agreements between member companies and HCPs for the study must be clearly defined, constitute part of the investigator and company files, and any remuneration should be fair and reasonable.

**9.2.10** Payment to researchers must not be based on continuing administration of the medicine under study to patients after the researcher has completed the study protocol.

**9.2.11** Material provided to the physician to outline the protocol, procedure, patient treatment and collection of data in a study should be clear and concise. The material should not incorporate the branding of the product, i.e. colours, images or other marketing/mnemonic devices that are an extension of the advertising material.

**9.2.12** Any correspondence or presentations to investigators during the course of a study should have no product or branding claims.

**9.2.13** If product is supplied to the physician to use in the study, it should be labelled "For clinical trial use only".

**9.2.14** Investigator meetings in the context of studies can be organized for any of the following reasons: a) review the protocol; b) review working processes; c) review of SAE, ICH and GCP guidelines; d) training of investigational site personnel in study conduct; e) review study progress and issues; or f) review the results of the study in which they participated. The attendees at such meetings should be limited to company personnel from the medical/scientific departments and if warranted, other company personnel who have an essential role in the functioning of the study from the design, conduct or management perspective.

When these studies are national only in scope the meeting must be held in Canada.

Section 13.6 should be referred to with regards to social interaction.

All standard communications with investigators in preparation for the meeting should be worded accordingly.

## 10. PRICE-RELATED MATTERS

**10.1** All Members must abide by federal and provincial laws and regulations relating to market pricing. Rx&D supports the principle of Actual Acquisition Cost (AAC). All Members shall cooperate with provincial governments to enforce this principle.

**10.1.1** Actual Acquisition Cost is defined as the true transaction cost of a medicine, including the direct and/or indirect benefits that accrue to the purchaser.

## 11. SERVICE-ORIENTED ITEMS

### 11.1 General Principle

Members must ensure that the distribution of service-oriented items is not carried out for product promotional purposes. Members must not conduct “special promotions” which cannot be justified if subjected to scrutiny by members of the health professions and the public. Members should also use good judgement by choosing modes of advertising that will uphold this general principle.

**11.2** Members may distribute acceptable service-oriented items to health care professionals. Acceptable service-oriented items are defined as items whose primary goal is to enhance the health care professional’s/patient’s understanding of a condition or its treatment. Such items may bear the corporate name and logo of the donor, but must not bear the name of any medicine.

The following are some examples (but not limited to) of service-oriented items that have been consistently ruled by the Industry Practices Review Committee (IPRC) to be in contravention of the Code:

- Agendas, bookmarks, calendars (desktop & wall);
- Calendar pads, daybooks, desk clocks;
- Diaries, fridge magnets, kit folders;
- Mouse pads, note pads, Obus Forme back supports;
- Paperweights, pens & penholders, plastic portfolios;
- Pocket diaries, Post-it Notes, stirrup covers;
- Stress/rehabilitation balls and similar so-called patient aids;
- Stationery items, such as patient appointment cards containing patient information;
- Product-bearing advertising;
- Tote bags (single sponsorship); and
- Bags with a corporate logo (single sponsorship).

**11.3** Each part of a multi-component service-oriented item must comply with Sections 11.1 and 11.2.

## 12. MARKET RESEARCH

### 12.1 Definition

Market research links the consumer, customer and public to the marketer through information - information that points out and defines marketing opportunities and problems; information that generates, refines, and evaluates marketing programs; information that monitors marketing performance; and information that improves understanding of marketing as a process.

Market research details the information needed to address these issues, designs the method for collecting information, manages and implements the data collection process, analyzes the results, and communicates the findings and their implications. This section applies to market research carried out within the framework of various activities including studies, individual and group interviews, and focus groups, etc.

### 12.2 General Principle

**12.2.1** The purpose of an individual or group interview must be made clear to the participant(s).

**12.2.2** Market research must not be a disguise for selling or developing sales contacts.

**12.2.3** Market research must not deliberately sway the opinion(s) of the participant(s).

**12.2.4** Honoraria offered to health care professionals who gather or provide market research information should be based on rates similar to (and not higher than) their usual rate of pay.

**12.2.5** Even when a consent form is signed, the confidentiality of participant(s) must be preserved. The identity of the participant(s) must not be revealed for purposes of promoting Member products to them in the future.

**12.2.6** Direct contact and administration with the participants in the market research project should be limited to marketing research personnel only with no sales representative involvement. There should be no follow-up by sales representatives derived specifically from the market research contacts.

**12.2.7** The market research questionnaire or program should not be designed in a manner that could be interpreted to be leading to a specific product conclusion.

HCPs should not leave any market research meetings with any kind of promotional material. Members are committed to separating market research from other types of activities.

## 13. ADVISORY BOARDS/CONSULTANTS

### 13.1 General Principle

**13.1.1** It is recognized that Members will seek advice and guidance from health care professionals in the conduct of various aspects of their business operations, including but not limited to, product development, research program, medical/scientific, and marketing issues. On such occasions, health care professionals assume the consultant's role providing advice, knowledge, and expertise to the Member.

**13.1.2** It is recognized that advisory boards/consultants panels may be constituted at the regional, provincial and national levels. This will ensure the selection of individuals who have recognized expertise in the areas in which the advice is needed, and that such advice reflects any geographical differences in attitudes/medical practice, procedures, etc.

### 13.2 Definitions

**13.2.1** To ensure consistency of terminology across Members, one should refer to "Advisory Board" when there is a contract/agreement between the consultant and the Member, enabling the individual to achieve a degree of familiarity with the Member and its operations. Generally, the purpose of these Advisory Boards is to advise Members on aspects of the development of a drug discovery to maturity (from pre to post launch).

**13.2.2** "Consultants panels/meetings": when a meeting is held with a specific group of experts where input is required to develop plans for product issues or opportunities.

**13.3** When entering into such arrangements, Members must be guided by the following:

- The purpose and objectives of the interaction must be clearly defined by the Member in its initial correspondence on the event;
- There must be a written contractual agreement confirming the purpose and objectives of the consultation outlining the nature of the services to be provided.

Documentation relevant to the consultation and its identified objective should be attached to the contractual agreement; and

- Remuneration must be in the form of an honorarium (fair and reasonable). Travel, accommodation and out-of-pocket expenses in providing the consulting service, where warranted, may be reimbursed.

### 13.4 Number of Advisory Board Member/Consultants

The number of advisory boards/consultants meetings must be limited. Members may only have a limited number of advisory boards/consultants meetings consistent with the need to gather scientific input or commercial guidance.

An advisory board/consultant panel may not include more than 20 healthcare professionals per meeting.

### 13.5 Meeting Location

Meetings of advisory boards/consultants panels must be held in Canada. The only exception is that they may be held in conjunction with international CHE events (Section 4B) provided that no travel or accommodation expenses are to be paid by the Member convening the meeting. If the advisory board meeting occurs before or after the international event ends, the Member may reimburse the HCP for room accommodations in conjunction with the advisory board.

### 13.6 Social Interaction

No social activity should be organized in conjunction with advisory boards/consultants panels other than providing refreshments or a modest meal. The guidelines with respect to travel and hospitality for CHE programs set out in Section 4.A.3.8 also apply to travel and hospitality related to advisory boards/consultants panels.

### 13.7 Participation

As the purpose of the activity is to seek consultation, at least one person from Head Office must be present to guide the meeting discussion.

Involvement of sales representatives and their direct supervisors is prohibited.

### 13.8 Special Circumstances

- Meeting organized by Corporate Head Office (international affiliate)

An advisory board/consultants panel may be organized by International affiliate. These meetings if held outside of Canada may include a maximum of 10 Canadian health care professionals, per brand, per year (experts in their fields). Honorarium and reimbursement of travel and accommodation expenses may be provided. As indicated in Section 13.3 above, contractual agreements should be entered into for these meetings as well.

## 14. PRIVACY OF PATIENT INFORMATION

14.1 All Members must abide by federal/provincial/territorial laws and regulations pertaining to privacy of patient information.

## 15. ENFORCEMENT

15.1 Complaints about any breach of this Code should be sent in writing to the Industry Practices Review Committee (IPRC) at Rx&D's Ottawa office. The IPRC will decide on the validity of the complaint. Complaints regarding potential Code breaches that are determined to have occurred more than one hundred and twenty (120) days after the event(s) giving rise to the complaint(s) became known to, or reasonably ought to have been known to, the complainant, will not be considered by the IPRC.

### 15.2 Response Time

The IPRC will convene within two weeks of receipt of written notification to decide on the validity of the complaint.

#### 15.2.1 Valid Complaint

The IPRC will adjudicate the complaint during the meeting and will render a decision when the Committee is convened, if possible, or no later than three business days following the meeting. The IPRC decision will be written and provided to the parties involved no later than three business days following the decision.

#### 15.2.2 Invalid Complaint

Should the IPRC determine the complaint is invalid; the IPRC will reject the complaint with a written explanation, while the Committee is convened.

### 15.3 Violations

Each unique violation as determined by the IPRC shall normally count as one (1) violation. However, it is within the discretion of the IPRC to count any

violation as two (2) violations, if it determines that such violation is intended to deliberately contravene the Code. A violation will be deemed to be deliberately in contravention of the Code when it is clearly not in compliance with any one of the Guiding Principles listed in Section 1.

### 15.4 Penalties

The following penalties apply to Members, which violate the Code during a 12-month calendar year:

- Upon first violation: Publication of the infraction in the Rx&D Update and a fine of \$10,000;
- Upon second violation: Publication of the infraction in the Rx&D Update and a fine of \$15,000;
- Upon third violation: Publication of the infraction in the Rx&D Update, a fine of \$25,000, and, the chief executive officer (CEO) of the Member must appear before the Rx&D Board of Directors (BOD), at which time he/she must provide a detailed explanation of the violations and a comprehensive written action plan to ensure remediation; and
- Each additional violation after a third one: Publication of the infraction in the Rx&D Update and a fine of \$50,000.

### 15.5 Repeat Offenders/Recidivists

In the event that any Member has five or more violations in one calendar year, or has two successive calendar years with at least three violations in each calendar year:

The Rx&D Executive Committee (EC) will convene and place the Member with such violations on a 12-month probationary period; probationary period to begin immediately following the EC decision. The probationary measures to be directed by the EC shall include, but may not be limited to, the following:

- CEO will provide a written and verbal update quarterly at BOD meetings for a 12-month period, beginning at the next scheduled BOD meeting, regarding remediation actions taken;
- Rx&D will communicate in writing with the CEO and Chair of the Board of the Member and its parent company, informing them of the situation;

The Member will communicate its probationary status to all health care professionals involved in its infractions indicating the sections of the Code violated as well as the steps the Member will be taking to ensure that they abide by the Code in the future; and

- If the Member is found in violation of the Code during its probationary period, the EC will reconvene to determine if the violation is a just cause for the following action:
  - Expulsion from Rx&D. In the event that a Member is expelled from Rx&D, notice of such shall be posted on the Rx&D Web site.

### 15.5.1 Deliberate Contravention

Any action found to deliberately contravene any of the Guiding Principles (Section 1) may be a just cause for expulsion. The BOD has discretion to determine if any other action is just cause for expulsion.

### 15.5.2 Urgent Hearing

The EC can hold a hearing when the matter is concerning a deliberate contravention of one of the Guiding Principles.

### 15.5.3 Membership Reapplication

The Company may reapply for membership after a 24-month period upon providing evidence of its improved compliance environment. The readmission is subject to the BOD's approval.

### 15.6 Appeal (process open to both parties)

Should either party not accept the IPRC decision, or should the IPRC not be able to decide on the matter, either party involved in the complaint has recourse to an appeal.

**15.6.1** The parties to the appeal shall be:

- A representative of each of the parties involved in the complaint;
- A representative of the IPRC, appointed by the President of Rx&D; and
- A panel of three arbitrators:
  - To which the parties have agreed upon;
  - The arbitrators must have expertise pertaining to the matter of the complaint; and

- If no agreement is reached on the choice of one or more of the three potential arbitrators within five business days of the nomination of any arbitrator, the President of Rx&D shall appoint them at his/her own discretion.

**15.6.2** The notice of appeal must be sent in writing to the IPRC, at Rx&D's offices in Ottawa, within 10 business days of receipt of the IPRC's decision.

**15.6.3** The appeal must be heard within four weeks of receipt by the IPRC of the notice of appeal.

**15.6.4** The panel will render its decision while the Panel is convened, when possible, or no later than three business days following the hearing.

**15.6.5** The panel decision will be provided in writing to the parties no later than three business days following the hearing.

**15.6.6** The panel decision shall be final, and the Member in question must adhere to it as a condition of continued membership in the Association. Such decisions shall be implemented immediately, including necessary remedial action related to the violation(s).

### 15.7 Cost

- Any costs incurred by any of the parties (Members) involved in the appeal, must be paid by them, respectively;
- Cost resulting from the appointment and participation of the arbitrators' panel will be paid by the party which loses the appeal; and
- When a complaint is found to be invalid by the IPRC, the complainant will pay any cost incurred to convene the IPRC.

### 15.8 No Appeal is Filed

If no appeal is filed in the time frame described in 15.6.2, the IPRC's decision will be considered final and the Member found in violation of the Code must adhere to the decision as a condition of continued membership in Rx&D.

### 15.9 Industry Practices Review Committee

Formerly known as the Marketing Practices Review Committee (MPRC).

### IPRC MEMBERS

**Permanent members and one to two ad hoc members will form the IPRC:**

- Two Member representatives, as appointed by the BOD;
- Two external representatives, health care professionals appointed by the BOD;
- The lead of the IPRC as appointed by the Rx&D President; and
  - Rx&D's General Counsel.

**Additional members can be:**

- One individual appointed by the Rx&D President;
- One representative from Pharmaceutical Advertising Advisory Board (PAAB), as required; and/or
- One external representative from the scientific community, as required, as appointed by the IPRC.

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