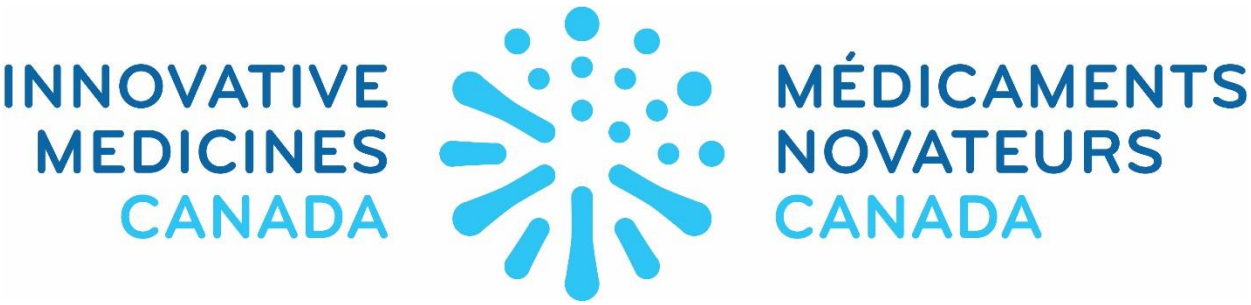

2018

CODE OF ETHICAL PRACTICES

TABLE OF CONTENTS

INTRODUCTION

Canada's Research-Based Pharmaceutical Companies (Innovative Medicines Canada) 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.

Mission Statement

As the national voice of research-based pharmaceutical companies, Innovative Medicines Canada advocates for policies that enable the discovery, development and commercialization of innovative medicines and vaccines that improve the lives of all Canadians. We support our Members' commitment to being valued partners in the Canadian health care system.

Scope

This Code applies to the activities of all Member employees who interact with Stakeholders for the purpose of commercializing prescription medicines, excluding medical devices and over-the-counter products, through interactions between Members and Stakeholders. Adherence to the Code is a condition of Membership.

Definitions

Advertising: "Advertising" is defined by Health Canada as including any representation by any means whatever for the purpose of promoting directly or indirectly the sale of any drug. In determining whether a message falls within the definition of advertising, the purpose of the message is very significant. It must be determined whether the primary purpose of the message is to promote the sale of a drug or to provide information.

Dissemination of information: The term "dissemination of information" includes both the dissemination of scientific information and advertising.

Dissemination of scientific information: The term "dissemination of scientific information" refers to any activity undertaken, organized or sponsored by a Member which is directed at Stakeholders relating to the prescription, recommendation, supply, administration or consumption of its prescription medicines or relating to a disease state.

Industry Practices Review Committee (IPRC): The term "Industry Practices Review Committee" (IPRC) refers to the body that adjudicates complaints as further described in Section 19 of this Code.

Innovative and/or Patented Prescription Medicines in Canada: The term "innovative and/or patented prescription medicine in Canada" applies to a prescription drug or vaccine for which the Member has patent exclusivity and/or data exclusivity.

Member Employee: The term "Member Employee" relates to an employee of a Member company (Member) acting in that capacity or any person retained by a Member that acts on behalf of the company.

Member: The term "Member" or "Member companies" applies to all the Members of Innovative Medicines Canada.

Stakeholders include:

> **Government:** The term "Government" means a body of people that sets and administers public policy, and exercises executive, political, and sovereign power through customs, institutions, and laws within Canada or a Canadian province or territory.
>
> **Health Care Professional:** The term "Health Care Professional" means a person who by education, training, certification, or licensure is qualified to and is engaged in providing health care. This can include any of the following: an individual who is currently practicing medicine, nursing, or dispensing medicines in Canada or any other person who, in the course of his or her professional activities, may prescribe, recommend or administer a prescription medicine or be involved in related treatment or disease management.
>
> **Other Stakeholder:** The term "Other Stakeholder" means any individual or organization, other than Health Care Professionals and Government, who in the course of their activities, has an interest in or is impacted by the activities of a Member company. This could include involvement in the supply or purchase of a prescription medicines.

GUIDING PRINCIPLES

1.1. Purpose

The innovative pharmaceutical industry recognizes that Canadians expect companies to be accountable for their conduct. The Innovative Medicines Canada Code of Ethical Practices (the Code) provides a mechanism for Members to establish and maintain an ethical culture through a committed, self-regulated approach. As they collaborate with Stakeholders, Members recognize that they should be cognizant of the ethical requirements which apply to Health Care Professionals, Other Stakeholders and Governments.

The Guiding Principles are intended to provide interpretations of the Code and to assist Members where no specific provisions of the Code apply.

The Guiding Principles and detailed provisions of the Code set out standards for the activities of all Member employees relating to the commercialization of Prescription Medicines to ensure that Members' interactions with Stakeholders are appropriate and perceived as such.

Member Companies agree to adhere to the following Guiding Principles:

1. The health and well-being of patients and all Canadians is our first priority.
2. All interactions with Stakeholders are to be conducted in a professional and ethical manner. We must be cognizant of potential conflicts of interest and manage them appropriately.
3. All interactions shall be in accordance with all applicable laws and regulations.
4. We must adhere to the Code in both the spirit and the letter and, as such, we must ensure that all relevant Member employees and agents acting on our behalf are appropriately trained in the requirements of the Code and abide by it.
5. We are committed to engaging in relationships that are trustworthy and credible.
6. All clinical (phase I to IV) trials and scientific research sponsored or supported by Members will be conducted with the intent to develop knowledge that will benefit Canadians and advancement of science and medicine. We support transparency in the presentation of research and study results.
7. We will ensure that Canadian Stakeholders have access to education and information about the appropriate uses of our products and services. All product information provided to Stakeholders must be accurate and fair balanced.
8. We will not give or offer any payments or inducements that are either unlawful or improper, directly or indirectly, to any individual stakeholder.

PRIVACY OF PATIENT INFORMATION

2.1 Privacy of Patient Information

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

TRANSPARENCY

3.1 Transparency of product information

3.1.1 Material relating to prescription medicines and their uses, whether promotional in nature or not, which is sponsored by a Member in part or in whole must clearly indicate by whom it has been sponsored. The declaration must accurately reflect the nature of the Member's involvement.

3.2 Transparency in authorship

3.2.1 Members believe that Health Care Professionals should always be responsible and have full editorial control of the content of any publication or presentation that is disseminated or presented in their name. In some circumstances, it is reasonable to expect that professional writing services are provided to authors to support the development of content for a publication or presentation. In these cases, the responsible author is expected to review the content in its entirety and assume full responsibility for said content. The writing support must be mentioned in the acknowledgment section of the publication or presentation.

3.3 Guidelines for Transparency in Funding of Patient and Advocacy Groups and Patient Associations

3.3.1 The Innovative Medicines Canada Guidelines for Transparency in Stakeholder Funding annexed to this Code are considered an integral part of the Code as it pertains to patient and advocacy groups and patient associations **(Annex A)**.

3.4 Disclosure

3.4.1 Members are encouraged to appropriately acknowledge support they provide and to ask recipients to do so.

3.4.2 Where congresses, symposia, conventions and similar events are sponsored in whole or in part by a Member, such sponsorships should be appropriately disclosed.

3.4.3 Upon a Health Care Professional's request, Member employees must inform him/her that they have prescription data information available from various sources.

MEMBERS' EMPLOYEES

4.1 General Principle

4.1.1 Member employees represent both their company and the pharmaceutical industry as a whole in the eyes of Stakeholders. They are the main point of contact between the pharmaceutical industry and Stakeholders in Canada's health care sector.

4.2 Standards for Employment and Training

4.2.1 Member employees must act in accordance with the highest professional and ethical standards at all times. They are expected to understand and abide by the Code whenever they are acting in a professional capacity.

4.2.2 Members must ensure that all employees who are employed by or acting on behalf of the Member Companies have the credentials required to fulfill the role they are performing for their Company. In particular, Members must ensure that positions requiring significant levels of scientific or medical knowledge are filled with employees who have relevant degrees and certification.

4.2.3 Members must ensure that all employees who are employed by or acting on behalf of the Member Companies receive training about the applicable laws and regulations that govern the employees' interactions with Stakeholders as well as this Code.

4.2.4 Members must also train their employees interacting with Stakeholders on products and disease states, specifically:

4.2.4.1 All employees, should have sufficient knowledge of their subject matter, reflecting the requirement of their professional practice. Employees interacting with Health Care Professionals must have sufficient knowledge of general science and product specific information to provide accurate and up-to-date information. Members are responsible for ensuring the rigor and timeliness of such training.

4.2.4.2 Member employees whose job functions include responsibility for Continued Health Education (CHE) development and design as well as other relevant professionals must take a certified course in CHE training prior to or within one year of attaining responsibility for CHE activity.

SCIENTIFIC EXCHANGES

5.1 Promotional Activities

5.1.1 General Principles

5.1.1.1 Members must provide full and factual information on products, without misrepresentation or exaggeration. Statements must be accurate and complete. They should not be misleading, either directly or by implication.

5.1.1.2 With respect to their promotional activities, Members agree to comply with all applicable provisions of Health Canada (HC) regulations, the Code of Advertising Acceptance of the Pharmaceutical Advertising Advisory Board (PAAB) and the Code of Advertising Standards of Advertising Standards Canada (ASC). A breach of the PAAB and/or ASC Codes or Health Canada Guidelines may be deemed by the IPRC to be a breach of this Code.

5.1.1.3 Occasional reasonable meals/refreshments may be offered in connection with promotional presentations by Member employees to Health Care Professionals and other Stakeholders attending the presentation.

5.1.1.4 Members will not promote prescription medicines that are not approved in Canada or unauthorized uses of approved prescription medicines. Promotion of unauthorized prescription medicines and uses is prohibited irrespective of an employee's function within the Member company.

5.1.1.5 Members' promotional activities must never involve pro-active or solicited discussion of off-label indications, uses, dosages, or populations and must be consistent with the approved prescribing information in the product monograph.

5.1.2 Signing of Promotional Materials by Medical/Scientific Personnel

5.1.2.1 Member's promotional materials are communications whose purpose is to advertise a Member's product(s). Such communications must not be signed by Member employees who work in medical, regulatory or medical/scientific information services. Member employees who work in those areas may, however, sign the following types of communications, including without limitation:

a. Responses to medical/scientific information requested by a Health Care Professional;
b. 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).

5.2 Non-Promotional Activities

5.2.1 General Principles

5.2.1.1 The prohibition against off-label promotion is not intended to restrict the non-promotional exchange of scientific information or the right of the scientific community and the public to be fully informed concerning scientific and medical progress.

5.2.1.2 Occasional reasonable meals/refreshments may be offered in connection with non-promotional presentations by Member employees to Health Care Professionals and other Stakeholders attending the presentation.

5.2.2 Standards

5.2.2.1 Requests for information on unauthorized products or uses will be referred to the Member's medical department.

5.2.2.2 Legitimate circumstances exist for Members' qualified scientific and medical personnel to communicate scientific information about their prescription medicines for optimal patient care in response to specific unsolicited queries and in the context of research activities and scientific exchange.

5.2.2.2.1 Communication of off-label scientific information must be distinct and separate from promotional activities.

5.2.2.2.2 Responses to queries concerning unauthorized products or uses must disclose clearly that the information concerns unauthorized products or usage and must also clearly state the approved product indication.

5.2.3 New Product Information

5.2.3.1 Members should take all reasonable measures to ensure that Health Care Professionals are informed in a timely manner with respect to all new product information and ensure that this product information (such as the product monograph or excerpts from it) is sent to drug information centres, poison control centres, faculties of medicine, national medical associations and pharmacies across Canada, before the product is launched.

BUSINESS MEETINGS AND DISCUSSIONS

6.1 General Principles

6.1.1 Members recognize their responsibility in ensuring that the selection of venues is appropriate and conducive to the purpose of the business meeting or events they organize. Members may provide reasonable meals/refreshments to Stakeholders. The provision of meals/refreshments must be ancillary to the activity associated with it. For business meetings and events held outside of Canada, Members must respect the applicable laws, regulations and self-regulatory Codes of the country where the business meeting or event is being held.

6.1.2 No other form of stand-alone hospitality or entertainment is to be provided and the provision of tickets or vouchers, is not permitted, with the exception of hospitality related to a charity event as referred to in Section 12.2.2 of this Code.

6.1.3 Member employees should not participate in activities such as but not limited to golf, hockey, theatre and spa in interactions with Stakeholders outside of the limited exceptions as described in Section 12.2.2 or as part of congresses/symposia that are incidental to these events and which are not organized by Member companies.

6.2 Venues

6.2.1 Members must conduct business meetings and/or events in an appropriate setting conducive to learning or conducting a business discussion.

6.2.2 Members must avoid venues that are excessive or extravagant in nature. Where some hotels or other venues have adequate conference facilities but may be perceived as luxury resorts where the emphasis is on leisure and recreation, Members should consider the choice of such venues carefully and be able to reasonably justify their choice of venue.

6.2.3 As the interpretation of reasonable can clearly vary across the country depending on city or province, the onus is on Members to ensure that the venue is not excessive or be perceived as such.

6.2.4 Business meetings and/or events must not be held in personal residences.

6.2.5 Under no circumstances shall a Member 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 to gain access to a Health Care Professional. Paying for a meeting room in a medical building is acceptable if required for a business discussion and provided the "fee" is within fair market value for a dedicated meeting room and is not paid directly to an individual Health Care Professional.

6.3 Provision of Meals and Refreshments

6.3.1 General Principle

6.3.1.1 The provision of reasonable meals and refreshments to Stakeholders is considered acceptable as long as the primary objective of the interaction is to facilitate business discussions.

6.3.2 Standards

6.3.2.1 The number of Stakeholders attending a business discussion, excluding promotional or learning programs that are covered in Sections 5, 9 and 10 of this Code, must be reasonable and justifiable if subjected to scrutiny by Stakeholders. Honorarium must not be provided to Stakeholders attending a business discussion.

6.3.2.1.1 Member employees may invite a maximum of five (5) Stakeholders, per informal interaction, per Member company. Although there may be more than one employee from a Member in attendance, the number of Stakeholders cannot be increased to result in larger groupings.

6.3.2.1.2 Member employees other than sales representatives and their direct supervisors may invite more than five (5) Stakeholders, per interaction, per Member Company when the legitimate purpose of such business discussion is documented through an agenda or through any other acceptable form of documentation.

6.3.2.2 Attendance to a business discussion is limited to invited Stakeholders. Under no circumstances can meals and refreshments be extended to their spouses/companions or their administrative staff.

RETAINING THE SERVICES OF A STAKEHOLDER

7.1 General Principles

7.1.1 Agreements with Stakeholders allow Members to obtain information and/or advice from experts.

7.1.2 Subject to Section 7.2, Members may retain Stakeholders, whether in groups or individually and compensate them for their services, travel and other expenses in connection with activities such as speaking at and/or chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, participation in market research, development of material or other related services.

7.2 Standards

7.2.1 The agreements between Members and Stakeholders must be in writing and, to the extent relevant to the particular agreement, must fulfill all the following criteria:

- A legitimate need for services must be clearly identified in advance of requesting the services and entering into an agreement with the prospective Stakeholder. The selection of the Stakeholder must be based solely on his/her qualifications to provide the service required;
- The number of Stakeholders retained must not be greater than the number reasonably necessary to achieve the identified need;
- The hiring of the Stakeholder to provide the relevant service must not be an inducement for: prescribing, supplying, recommending, buying, selling, access, reimbursement or favoring Members' products;
- Compensation for the services (or honorarium) must be reasonable and reflect the fair market value of the services provided. Reimbursement of reasonable out-of-pocket expenses, including travel and accommodation, may be provided where the Code allows it. Payments must never be in cash;
- Agreements must specify the nature of the services to be provided and the basis for payment of those services.

CONSULTANT MEETINGS

8.1 General Principles

8.1.1 Where appropriate, Members may retain Stakeholders to perform professional services including, but not limited to, consulting meetings and advisory boards and all of the above being referred to as consultant meetings for the purpose of this section.

8.1.2 The purpose of consultant meetings is to advise Members on aspects of the development of a drug discovery to maturity (from pre- to post-launch), on various aspects of their business or to provide input when required to develop plans, policies, etc.

8.1.3 An advisory board consists of a continuous relationship with a limited group of Stakeholders that meet on multiple occasions during their mandate to advise Members on different aspects of their business.

8.1.4 A consultant meeting is an ad hoc meeting held with an individual or a group of expert Stakeholders where input is required on a specific aspect of the business.

8.2 Standards

8.2.1 When entering into a consultant meeting agreement, Members must ensure that:

- The purpose and objectives of the interaction are clearly defined in the initial correspondence related to the event or in the ongoing advisory relationship agreement;
- There is a written agreement confirming the purpose and objectives of the consultation and outlining the nature of the services to be provided in accordance with the requirements set out in Section 7 of this Code; and
- Remuneration must be in the form of an honorarium and reasonable travel, accommodation and out-of-pocket expenses where warranted may be reimbursed in accordance with the requirements of Section 7 of this Code.

8.2.2 Number of meetings and consultants

8.2.2.1 The number of consultant meetings must be limited. Members may only have a number of consultant meetings that is consistent with the need to gather scientific input or commercial guidance.

8.2.2.2 The formation of multiple advisory boards for a single product must be justifiable, for example, as a result of registered indications in different medical specialties. It may be justifiable to have multiple advisory boards where there are recognized differences in medical practice between provinces and regions.

8.2.2.3 Consultant meetings may not include more than twenty (20) individual consultants per meeting, excluding, chairs, presenters and facilitators.

8.2.3 Meeting Location

8.2.3.1 Consultant meetings must be held in Canada. The only exception is those held in conjunction with international conferences (Section 10.2 of this Code) provided that no travel or accommodation expenses are to be paid by the Member convening the meeting. If the consultant meeting occurs before or after the international conference ends, the Member may reimburse the Stakeholder for room accommodations in conjunction with the consultant meeting.

8.2.3.2 Selected venue must be in accordance with Section 6.2 of this Code.

8.2.4 Social Interaction, Travel, Meals and Refreshments

8.2.4.1 No social activity should be organized in conjunction with consultant meetings other than providing refreshments or a reasonable meal.

8.2.4.2 The guidelines with respect to travel and provision of meals and refreshments for Learning Programs set out in Sections 9.2.5 and 9.2.9 of this Code also apply to consultant meetings.

8.2.5 Participation

8.2.5.1 At least one person from the Canadian Member's head office must be present to guide the meeting discussion. Involvement of sales representatives and their direct supervisors in the meeting is prohibited.

8.2.6 Special Circumstances – Consultant meetings organized by a Member's global head office and/or international affiliates

8.2.6.1 A consultant meeting may be organized by a Member's global head office and/or an international affiliate. If held outside of Canada, these consultant meetings may include a maximum of ten (10) Canadian Health Care Professionals, per indication, per brand, per year. Honorarium and reimbursement of travel and accommodation expenses may be provided in accordance with Section 8.2 of this Code. As indicated in Section 8.2.1 above, written agreements should be entered into for these meetings as well.

LEARNING PROGRAMS FOR HEALTH CARE PROFESSIONALS

9.1 General Principle

9.1.1 To facilitate the transfer of knowledge and skills among qualified Health Care Professionals, Members may support accredited and unaccredited programs delivered by Health Care Professionals for Health Care Professionals and other relevant collaborators to facilitate their learning. Accredited and unaccredited programs, irrespective of format, serve to enhance knowledge and understanding of advances in health research, health sciences, clinical practice and professional development so that Health Care Professionals can, in turn, provide superior health care to Canadian patients.

9.2 Standards

9.2.1 Topics must not be promotional-oriented and presentations must give a balanced view of all relevant therapeutic options available.

9.2.2 Innovative Medicines Canada supports the principle of disclosure by Health Care Professionals of any financial or any other material affiliations with its Members.

9.2.3 Acknowledgment of sponsorship by Members should appear on all program-related materials.

9.2.4 The resources provided by a Member for planning, implementing and administering a learning program, such as financial or in-kind (such as human, organizational or technological), should be disclosed to enable each party to be aware of sources of funding and expenses through employing transparent accounting practices (e.g. an agreement outlining financial commitments).

9.2.5 Remuneration of the speaker or moderator must be in the form of an honorarium calculated at fair market value reflective of usual rates of compensation, and may only be provided after the service has been rendered. Reasonable travel, accommodation and out-of-pocket expenses, where warranted, and in line with this Code, may be reimbursed. Remuneration and/or reimbursement of expenses to other Health Care Professionals attending the learning program are prohibited.

9.2.6 Members commit to ensuring that full editorial control of presentation content resides with the Health Care Professional presenter or organizations.

9.2.7 Learning programs supported by Members or through a third party are designed for Health Care Professionals and invitations are to be extended only to Health Care Professionals and other relevant collaborators. These programs must not be offered to the spouses/companions or family members of Health Care Professionals. 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 travel, accommodation, meals and refreshments 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.

9.2.8 Members should not be involved in the development of or payment for entertainment in conjunction with any learning program or activity.

9.2.9 Where meals and refreshments are provided at learning programs, Members must follow the standards as outlined in Section 6 of this Code.

9.2.10 Attendance of Member Sales Representatives to learning programs is acceptable. Member employees cannot detail products at a learning program. However, it is appropriate to have a booth set up at a congress that is segregated from the learning program(s).

9.3 Continued Health Education (CHE) (Accredited Programs)

This Section applies to all Members and any third party retained by a Member who is involved in the development or implementation of Continuing Health Education (CHE) programs.

9.3.1 Definition

9.3.1.1 The term "Continued Health Education" (CHE) includes programs for all Health Care Professionals. The term "Continued Professional Development" (CPD) is included within the definition of CHE. Members are committed to separating CHE from promotional activities and any other activities in which Health Care Professionals receive a fee for service.

9.3.1.2 The purpose of CHE is to provide programs for Health Care Professionals which follow the content development, ethical guidelines, and have received accreditation from a professional organization such as:

- The Royal College of Physicians and Surgeons of Canada;
- The College of Family Physicians of Canada;
- The Federation of General Practitioners of Québec (FMOQ);
- The Federation of Medical Specialists of Québec (FMSQ);
- The Canadian Council on Continuing Education in Pharmacy (CCCEP); and
- Other Canadian organizations that provide credits that are recognized by CHE accrediting bodies.

9.3.2 Standards

9.3.2.1 All CHE programs and all CHE program-related materials must clearly identify the fact that final accreditation has been obtained.

9.3.2.2 To ensure professional standards for the industry, Member employees whose job functions include responsibility for CHE development and design as well as other relevant professionals must take a certified course in CHE training prior to or within one year of attaining responsibility for CHE activity.

9.3.2.3 Member employees other than CHE professionals must not be involved in any content development but may be involved in program logistics such as, but not limited to:

- Execution of agreements, where applicable;
- Distribution of invitations and collection of evaluations;
- Making arrangements for venue, incidental meals and refreshments in keeping with Section 6 of this Code; and
- Distribution of accredited learning program material (acceptable to attendees only).

9.4 Other Learning Activities (OLA) (unaccredited Health Care Professionals facilitated programs)

This Section applies to all Members and any third party retained by a Member who is involved in the development or implementation of activities that have not been accredited, but still involve the presenting of medical/scientific information to Health Care Professionals by Health Care Professionals.

9.4.1 Definition

9.4.1.1 "Other Learning Activities" are defined as unaccredited programs, events or activities, including self-directed learning programs that do not meet the accreditation criteria set out by the professional organizations listed above in Section 9.3.1.2. They are considered non-promotional in nature. Members must ensure that these activities aspire to high ethical standards, and are balanced.

9.4.1.2 These programs must not be referred to as "CHE" or "educational" as these terms are reserved for programs that are accredited.

9.4.2 Standards

9.4.2.1 Exchange of information on related scientific and clinical issues must be the primary focus of and reason for sponsoring or participating in an OLA program.

9.4.2.2 Member companies do not support product discussion that is not consistent with the approved prescribing information in the official product monograph. If a speaker or a moderator chooses to speak about unapproved uses of a product, they must be required by contract to inform the audience of this fact at the start of the presentation and a disclaimer should be written on the presentation.

9.4.2.3 Member sales representatives are limited to the following activities related to OLA programs:

- Logistics;
- Preparation of invitations;
- Recommendation of a speaker;
- Execution of agreements, where applicable;
- Distribution of invitations and collection of evaluations;
- Making arrangements for venue, incidental meals and refreshments in keeping with Section 6 of this Code; and
- Distribution of learning program material (acceptable to attendees only).

9.5 Preceptorships

9.5.1 Definition

9.5.1.1 Health Care Professionals' preceptorships are unique programs that should facilitate learning and transfer of skills and knowledge from one Health Care Professional to another. Preceptorships allow a Health Care Professional to spend time with a trainer who is a recognized expert in his/her field that can withstand external scrutiny, to gain a better understanding and insight into a therapeutic area or disease state.

9.5.2 Standards

9.5.2.1 To facilitate the transfer of knowledge and skills among qualified Health Care Professionals, Members may support a preceptorship program. Payment of honoraria calculated at fair market value reflective of usual rates of compensation for the services provided and reimbursement for the trainer's reasonable travel and accommodation expenses are permitted.

9.5.2.2 A maximum of five (5) Health Care Professionals, per calendar year, per brand, per specialty by indication, where specific indications call for interactions with Health Care Professionals from different specialties, may be sponsored to participate in a preceptorship program in an appropriate teaching center, being a teaching hospital, a teaching clinic or a university, in or outside Canada. Sponsorship is limited to reasonable travel and accommodations.

9.6 Speaker Training (Faculty Training) and Workshops

9.6.1 General Principle

9.6.1.1 For learning programs, irrespective of the format, on new products, new indications or disease state or significant label changes (i.e. patient safety), a need may arise to train an appropriate number of Health Care Professionals who are recognized experts on this information so as that they may disseminate this information to their colleagues for the benefit of Canadian patients. A product or indication is considered "new" up to one year after its initial marketing.

9.6.2 Definition

9.6.2.1 An appropriate number of Health Care Professionals may be trained on legitimate learning programs, new products, new indications or disease states or significant label changes (i.e. patient safety) for the sole purpose of disseminating this information at subsequent events. These training meetings are referred to as "Speaker Training" or "Faculty Training".

9.6.3 Standards

9.6.3.1 When Speaker training meetings should involve the selected group of recognized experts in the related field to meet at an appropriate venue within Canada, reasonable travel and related expenses including honoraria at fair market value for services may be paid to the trainer and trainees. Appropriate meals and refreshments may be provided in accordance with Section 6 of this Code; however, entertainment is prohibited. These Health Care Professionals must have a written agreement with the Member to participate in the meeting with the requirement to deliver subsequent training to other Health Care Professionals.

9.6.3.1.1 Members must use professional judgment and have only a reasonable number of speaker training sessions consistent with the need to train this select group of Health Care Professional experts/leaders.

9.6.3.1.2 Speaker training sessions may not include more than twenty (20) Health Care Professional trainees per meeting. The Health Care Professional trainers are excluded from this number.

9.6.3.2 A Member's decision regarding the selection or retention of Health Care Professionals as speakers should be made based on defined criteria such as general medical expertise and reputation, knowledge and experience regarding a particular therapeutic area, and communications skills.

9.6.3.3 The total number of trained speakers must be reasonable relative to the size of the relevant audience of Health Care Professionals.

9.6.4 Special Circumstances – Speaker Training by an Internationally Recognized Expert

9.6.4.1 Should the need arise for Canadian recognized experts to be trained by an internationally recognized expert from a country where the new product or new indication is available, Members have the following options:

- Invite the internationally recognized expert to Canada to conduct the training; or
- Send a maximum of five (5) Canadian recognized experts per new product or new indication to an appropriate teaching center, such as a teaching hospital, a teaching clinic or a university, to receive this training. Reasonable travel and accommodation may be reimbursed.

9.6.4.2 Speaker training by an internationally recognized expert can only occur after a Health Canada filing for a new product or new indication and within a reasonable timeline before the expected date of launch of the new product or indication.

CONFERENCES AND CONGRESSES

10.1 Support for Canadian Third-Party Educational or Professional Conferences and Congresses

10.1.1 General Principles

10.1.1.1 Members have a role to play in ensuring that Stakeholders are educated and kept informed on developments in health research, health sciences, clinical practice and their profession. Members may receive and consider requests for sponsorship of conferences and congresses organized by academic societies and professional associations or organizations.

10.1.1.2 These events must take place in Canada in order for this Section to apply.

10.1.1.3 Sponsorship of Canadian Professional Associations conferences or congresses hosted outside of Canada is prohibited.

10.1.2 Definition

10.1.2.1 A Canadian third-party educational or professional congress or conference is any activity, organized by specialty societies and/or academic institutions, held at an appropriate location where meals and refreshments are reasonable in nature, where the gathering is primarily dedicated, in both time and effort, to provide objective scientific and educational activities and discourse, and the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. These events must be approved, endorsed, or sponsored by academic societies or professional associations or organizations.

10.1.3 Standards

10.1.3.1 Members may sponsor Canadian third-party educational or professional conferences and congresses, under the following conditions:

10.1.3.1.1 The responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conference or congress in accordance with their guidelines.

10.1.3.1.2 The primary purpose of the event must be scientific, medical and/or educational in nature.

10.1.3.1.3 The audience may consist of Stakeholders, including patients or public.

10.1.3.2 In considering such requests, Members must comply with the following requirements:

10.1.3.2.1 The request for sponsorship must be received in writing, and must include all details of the funding requested through a variety of sponsorship levels (Platinum, Gold, etc.). Objective evidence of the educational value of the event is required (for example, an agenda or scientific program) that clearly describes the educational purpose, content, meeting start and finish times and duration of educational sessions. Members should undertake a review of the educational value prior to agreeing to sponsor the event.

10.1.3.2.2 The Member providing the support must respond to the request in writing, outlining the nature of the funding provided, clearly indicating to the requesting party what the Member is supporting.

10.1.3.2.3 It is appropriate for the Member to set up a booth or display in the exhibit hall of the conference or congress. In doing so, a Member must respect the conditions set out in Section 11 of this Code. Gifts, offers or enticements provided by a Member to encourage a Stakeholder to visit a display are prohibited.

10.1.3.2.4 As per Section 16.3.4 of this Code, a Member is not allowed to distribute samples at a conference or congress.

10.1.3.2.5 Product branding where permitted by the conference or congress must follow the guidance frameworks for promotion provided by Health Canada. As such, sponsorship of conference or congress items through the sponsorship level chosen is permitted. Individual Members cannot distribute branded items at a conference or congress.

10.1.3.2.6 Where conferences and congresses are sponsored in whole or in part by a Member, such sponsorships should be appropriately disclosed and accurately reflect the nature of the Member's involvement. Acknowledgment of sponsorship by Members should appear on all program related materials.

10.1.3.2.7 Where Members are involved in the sponsorship and/or distribution of reports on conferences and congresses, these reports might constitute promotional material and thus would be subject to the requirement of the Code. Names of the sponsoring Members should be clearly indicated.

10.1.3.2.8 Attendance of Member employees at Canadian third-party educational or professional conferences and congresses is acceptable.

10.1.3.2.9 As it relates to particular sponsorship, Member-specific social functions are not permitted. However, Member employees can participate in activities that are part of conferences and congresses if they are incidental to these events and are not organized by Member Companies.

10.1.3.2.10 Sponsorship of attendees to a Canadian third-party educational or professional conference or congress is prohibited.

10.2 Sponsorship of Stakeholders to International Conferences and Congresses

10.2.1 General Principle

10.2.1.1 In addition to their commitment to provide and promote high quality health education programs for Stakeholders in Canada, Members have a role to play in ensuring that Canadian Stakeholders are educated and kept informed on developments in health research, health sciences, clinical practice and their profession at the international level. Members may receive and consider unsolicited requests from individual Stakeholders, academic societies, and professional associations or organizations for financial assistance to participate in international 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 Stakeholders to international events is to improve health care for Canadian patients.

10.2.2 Definition

10.2.2.1 These are defined as international events that have been approved, endorsed, or sponsored by academic societies, or professional associations or organizations.

10.2.2.2 International events must take place outside of Canada in order for this Section to apply; when held in Canada, Section 10.1 applies.

10.2.3 Standards

10.2.3.1 Members may sponsor Stakeholders to attend international events, under the following conditions:

10.2.3.1.1 There is a legitimate educational purpose fulfilled in sponsoring the Stakeholder.

10.2.3.1.2 The venue must be appropriate for scientific or educational communications.

10.2.3.1.3 The primary purpose of the event must be scientific, medical and/or educational in nature.

10.2.3.1.4 The international event derives participants from many countries.

10.2.3.2 In considering such requests, Members must comply with the following requirements:

10.2.3.2.1 The request must be received in writing, and must include all details of the funding requested, the program, as well as the specifics of the educational program(s) to be delivered by the participant(s) on their return to Canada.

10.2.3.2.2 The Member providing the support must respond to the request in writing, outlining the conditions/requirements in exchange for the financial support.

10.2.3.2.3 As part of the sponsorship, Members may provide funding for reasonable transportation, lodging, meals, and registration fees relating to the sponsored event.

Reimbursement or payment of personal incidental expenses or any costs associated with accompanying family members are not eligible for reimbursement.

10.2.3.2.4 The Member must require the individual to advise whether or not he/she has requested support from more than one source to attend the same event. Funding from all sources is not to exceed total costs that are anticipated for items outlined in Section 10.2.3.2.3.

10.2.3.2.5 The individual(s)/organization(s) requesting the support must be required to share with Canadians the benefit of knowledge gained through one of:

a. The submission of a report or paper to the supporting Member;

b. Through a written report to a specialty society/academic institution; or

c. A verbal presentation to Health Care Professionals.

10.2.3.2.6 Such papers and/or presentations must include a statement by the author/presenter acknowledging that financial support by the Member to attend the international event was received.

10.2.3.2.7 Members may provide financial support for a maximum of ten (10) individuals per Member to any one international event. Financial support must be reflective of fair market value and be paid after the event upon proof of attendance or managed by the Member. Notwithstanding the provisions in Section 6.3.2 of this Code, a Member may provide reasonable meals and refreshments to all sponsored Stakeholders to an international event as per Section 6 of this Code.

10.2.3.3 In considering such requests, Members must ensure the request and sponsorship comply with this Code, as well as the laws and regulations of the country where the event will be held.

10.3 International Conferences and Congresses Held in Canada

10.3.1 General Principles

10.3.1.1 International events are sometimes held in Canada. As such, International Affiliates (non-Canadian) of Members may host or participate in scientific exchanges with Canadian and non-Canadian Health Care Professionals attending these events. These International Affiliates must respect applicable Canadian laws and regulations and this Code.

10.3.1.2 It is the responsibility of each Member to ensure the compliance of their International Affiliates with this Code.

10.3.1.3 Any incident of non-compliance by an International Affiliate with this Code could result in an infraction for the Member.

10.3.2 Standards

10.3.2.1 Company X materials used at the conference:

10.3.2.1.1 If the product is not approved for sale in Canada, the material used at the conference is to emanate from the parent company (Company X Inc.) and should be labelled as follows:

- "Product X (chemical name) is not available for sale in Canada" (or similar text, approved by the Canadian affiliate's regulatory and/or medical department – such disclaimer should be legible, and in proportionate size to the material displayed or presented.

10.3.2.1.2 If a product's indication(s) differ from those contained in the approved Canadian product monograph, the material used at the booth should be labelled with the following disclaimer:

- "The information contained herein does not necessarily reflect the content of the approved Canadian product monograph" or similar text, approved by the Canadian affiliate's regulatory and/or medical department – such disclaimer should be legible and in proportionate size to the material displayed or presented.

10.3.2.1.3 No reference should be made at the commercial booth and/or in the materials distributed as to the availability in Canada of unauthorized drugs through the Canadian Special Access Program or any off-label use.

10.3.2.1.4 All drug product materials, including posters, should be submitted to the Canadian affiliate's regulatory and/or medical department for review and approval.

10.3.2.1.5 Questions from Canadian Health Care Professionals relating to the availability of a drug prior to market authorization or for indications not-approved in Canada are to be referred to the Canadian Medical Department personnel or to the on-site Canadian medical personnel.

10.3.2.1.6 Product branding where permitted by the conference or congress must follow the guidance frameworks for promotion provided by Health Canada. As such, sponsorship of conference or congress items through the sponsorship level chosen is permitted. Individual Member Companies cannot distribute branded items at a conference or congress.

10.4 Stand-Alone Scientific Exchange Meetings Organized by Head Office of a Member Company

10.4.1 Definition

10.4.1.1 A "stand-alone meeting" is a scientific exchange meeting (excluding Investigator meetings), organized by the International Affiliate/Global Corporate Head Office of a Member Company, which involves Health Care Professional invitees from many different countries (including Canada) and is usually held in a central location, inside or outside of Canada.

10.4.2 Standards

10.4.2.1 Stand-alone meetings must be organized by the International Affiliate/Corporate Head Office.

10.4.2.2 Invitations to invitees must come from this International Affiliate/Corporate Head Office.

10.4.2.3 Members are limited to sending a maximum of ten (10) Health Care Professionals per event.

10.4.2.4 Members are permitted to pay for reasonable travel and accommodation of attending Health Care Professionals.

DISPLAYS

11.1 General Principle

11.1.1 Congress/clinic displays allow for enhanced interaction with Health Care Professionals. The main purpose of such displays must be the presentation of accurate information about the product(s) on display.

11.2 Standards

11.2.1 At least one qualified representative of the Member must be on site during congress hours.

11.2.2 Promotional and educational material available at the display must be consistent with the approved product monograph(s). 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 approved product monograph(s).

11.2.3 The fee a Member pays for exhibit space must not include additional donations to the association or other entity holding the congress, unless additional donations are reported as such.

11.2.4 Members must not pay for or make a donation to have displays set up on a continuous basis at clinics/hospitals.

11.2.5 Provision of meals and refreshments at the display is prohibited.

PROVISION OF FUNDING

12.1 General Principle

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

12.2 Standards

12.2.1 Donations, including donations in kind, may be provided to organizations involved in promoting activities such as 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 follow the guidance frameworks for promotion provided by Health Canada.

12.2.2 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, through the purchase of a foursome at a golf tournament, or other sporting activity, the individuals invited may be Stakeholders, with the exception of Health Care Professionals.

12.2.3 Funding may also be provided to groups or associations of Stakeholders to organize bona fide activities such as medical research, public policy research, education, and training or to support any project that will enhance patient outcomes or relate to continuing professional education, patient or community education or community projects that promote better health care. No support can be made to an individual Stakeholder with the exception of sponsorship of Health Care Professionals to attend an international conference or meeting event that is covered under Section 10.2 of this Code.

12.2.4 Members must ensure that there are no incentives to prescribe, recommend, purchase, supply or administer a product based on financial support and that nothing should be offered or provided which would interfere with the independence of a Health Care Professional's prescribing or dispensing practices.

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

12.2.6 Funding is documented in a written agreement outlining the nature of the funding provided.

12.2.7 Funding is clearly acknowledged and accurately reflects the nature of the Member's involvement.

LOAN OF MEDICAL EQUIPMENT

13.1 General Principle

13.1.1 In its role to enhance the health of Canadians, Members may partner with Health Care Professionals in programs/arrangements (Programs) to improve the prevention, diagnosis or treatment of diseases in a specific therapeutic area through the loan of medical equipment. To facilitate the development of these Programs, medical equipment can be loaned to Health Care Professionals actively participating in such Programs.

13.2 Standards

13.2.1 Programs must not be intended to gain access or influence, or to promote specific Prescription Medicines. They must be established to demonstrate how better prevention, diagnosis or treatment may improve patient health outcomes.

13.2.1.1 Programs must comply with the following conditions in order to safeguard the professional independence of participating Health Care Professionals:

- The program has clear and written objectives to improve patient prevention, diagnosis and treatment of disease;
- The program is approved by the Canadian Member's Head Office (no field initiatives);
- A written agreement defining the terms of the loan is signed by the Health Care Professional and senior authorized Head Office representative of the Member prior to equipment loans (no retroactivity) and include provisions setting out:
  - The program's objectives;
  - The contribution of the Member (including a detailed description of the medical equipment to be loaned);
  - The duration (cannot be indefinite), justified by the duration of the program;
  - The property title of the equipment will remain at all times with the Member;
  - That all loaned equipment will be returned to the Member at the expiration of the agreement; and
  - That Health Care Professionals must not invoice any payer (including provincial governments, patients, or insurance companies) for the use of loaned equipment.
- The participation of a Member Sales Representative must be limited to the establishment and implementation of these programs;
- The programs must maintain patient confidentiality;
- Tracking systems must be implemented to ensure all loaned equipment is returned to the Member once a program concludes; and
- Medical equipment may bear the corporate name and logo of the Member, but must not bear the name of any products or related acronyms.

PATIENT SUPPORT PROGRAMS AND MEDICAL PRACTICE ACTIVITIES

14.1 Definitions

14.1.1 Patient Support Programs

"Patient Support Programs" are programs offered by Member companies for the benefit of patients. The programs aim at increasing or facilitating patient understanding of a disease and/or treatment, bettering patient outcomes as well as possibly improving patient adherence to treatment. Such programs may also serve to ensure or assist with access and/or reimbursement of a product. The programs must have a primary objective of bettering patient health outcomes. Any benefit experienced by the prescribing or dispensing Health Care Professional must be incidental to the primary objective.

14.1.2 Medical Practice Activities

Medical Practice Activities are programs/services offered by Members to contribute to the Medical Practice's ultimate goal of bettering patient health outcomes via a comprehensive/holistic approach to medicine. The objective of these activities may be related to patient management practices and clinical outcomes management practices but must not be solely intended to improve or manage day-to-day administrative or operational responsibilities. Any benefit experienced by the prescribing or dispensing Health Care Professional must also be incidental to the primary objective.

14.2 General Principles

14.2.1 Intent

The Code recognizes that industry plays a vital role in supporting patients and medical practices for the purpose of enhanced patient outcomes and to benefit health care obtained by patients. However, these programs/services must not serve solely to cover day-to-day activities or resources considered part of the practice's operational expenses nor should they replace or compete with services or resources provided and funded by the existing healthcare system. Effort should be made for the healthcare system to absorb the cost of long-term initiatives.

14.2.2 Ensure Integrity of the Industry

When providing Patient Support Programs or support for Medical Practice Activities, the overarching principle is that the activity, whether provided by the Member directly or through a third party acting on the Member's behalf, should not bring the industry into disrepute. Member company staff/third-party vendors must have the requisite training and expertise so as to proceed in an ethical and professional manner. In addition, all elements of these programs/services should be appropriate, reasonable, and in accordance with treatment protocol/guidelines, clinical standards and relevant Code sections.

14.2.3 Conflict of Interest

These programs/services/ activities should never be offered nor provided to Health Care Professionals, Medical Practices, patients, their agents or healthcare facilities:

- As an incentive to gain access to a medical practice or hospital formulary listing;
- As an obligation or undue inducement to prescribe particular Prescription Medicines;
- In exchange for recommending for use; or
- In a manner that could be construed as a gift.

Any payment made to a Health Care Professional must be for appropriate services as described in a written agreement. Such payments must not be intended to cover acts or tasks that are part of the Health Care Professional's standard of care or which are covered as part of the healthcare system's reimbursement process.

Under no circumstances can the Health Care Professional acting as intermediary between Member company and patient be paid solely for offering the Patient Support Program to their patients.

All clinical decisions, which may include the selection of appropriate Prescription Medicines or the development of management plans, are the responsibility of the relevant Health Care Professional. Product-specific activities can be initiated only after the prescribing Health Care Professional has made the treatment decision and/or prescribed the product.

Such services/programs must never be sold, distributed or included on a claim for reimbursement or other submission for payment.

14.2.4 Design and Oversight

These programs/services/ activities must be designed and approved by the Canadian Member's head office so as to ensure proper design according to this and any other related section of this Code as well as the appropriate oversight.

14.3 Standards

14.3.1 Objective, Timelines and Scope

Patient Support Programs or Medical Practice Activities must have clear objectives, timelines and scope:

- The objective should be to achieve better patient health outcomes and/or facilitate access to a Member product.
- The timelines should be predetermined and justified by the clinical purpose.
- Consideration must be given to the appropriate use of the prescribed product (should the program involve a specific product) and the scope of the availability of the programs/services/ activities. Members are to design and offer programs/services to be intended for all eligible patients. If the program/services are to be limited in distribution, Members are to consider the criteria for eligibility to ensure a fair and appropriate dissemination.

14.3.2 Confidentiality, Transparency and Privacy

Members must be clear regarding information and communication with patients or medical practices whether it be done directly by the Member or through a third party acting on behalf of the Member:

- Patient confidentiality must be maintained at all times. In addition, proper privacy practices must be exercised in all such programs/services related to any potential data collected and the purpose of the collected data.
- Transparency regarding the Member Company or any third party acting on behalf of a Member is to be maintained in all programs/services / activities provided to patients or medical practices.
- In the case of the Patient Support Programs, the patient must subscribe or consent to a program and have the ability to opt out of the program at any given time and is to be provided clear instructions on how to do so.

Member companies should make all reasonable efforts to encourage the transparency by Health Care Professionals towards their patients regarding any financial or other material relationships with Members.

14.3.3 Data and Outcomes

Data collected, analysed, disseminated and/or published must be done according to current scientific standards and must be unbiased and accurate.

Key learnings or best practices collected from these programs/services can be used to illustrate the impact on health outcomes in scientific exchanges and promotional activities. Such findings may also be the subject of reports or other communications, provided that appropriate permissions and approvals are obtained.

14.4 Request for Support by Stakeholders

In some instances, Members may be invited or solicited by Health Care Professionals or Medical Practices to contribute or participate in an initiative they are leading related to patient management or clinical outcomes management. In such cases, Members are to evaluate the appropriateness of the request and their ability to contribute, whether it be by means of a financial contribution (see Section 12) or by offering a Patient Support Program or Medical Practice Activity as described in this section.

SERVICE-ORIENTED ITEMS

15.1 General Principles

15.1.1 Reasonable "service-oriented items" are defined as items whose primary goal is to enhance Health Care Professionals' understanding of a condition or its treatment or to assist Stakeholders to better perform their professional activities. Items intended for distribution to patients via a Health Care Professional must be useful as aids to patients' understanding of, or adaptation to, their condition(s) or for encouraging adherence with a recommended therapy. Such items may bear the corporate name and logo of the Member Company, but must not bear the name of any product.

15.1.2 Members may distribute acceptable service-oriented items to Stakeholders.

15.1.3 Members must not offer to any Stakeholder, or to any member of a Stakeholder's clinical/administrative staff and/or family, any gift – in cash or in kind – or any promotional aid, prize, reward, or any other item as an incentive or reward for prescribing, administering, recommending, purchasing, paying for, reimbursing, authorizing, approving or supplying any product or service sold or provided by the Member, or to obtain any other improper advantage for the Member.

15.1.4 Members must ensure that the distribution of service-oriented items is not carried out for product promotional purposes. Members should also use good judgment by choosing modes of advertising that will uphold this General Principle.

15.2 Standards

15.2.1 The following are some (but not all) examples of service-oriented items that – if provided in connection with a Patient Program or intended to aid the patient's understanding of, or adaptation to, their condition(s) or for encouraging adherence with a recommended therapy – would be considered acceptable service-oriented items within the Code:

- Patient agendas, Patient calendars;
- Patient diaries, fridge magnets, kit folders.

15.2.2 The following are some (but not all) examples of service-oriented items that – if provided to Stakeholders – would be considered acceptable service-oriented items within the Code:

- Textbooks of reasonable value;
- Websites, applications, screening program content;
- Educational tools and posters, anatomical models.

15.2.3 The following are some (but not all) examples of service-oriented items that – if provided to Stakeholders (outside of the exceptions outlined in 15.2.1 and 15.2.2) – would be considered to be in contravention of the Code:

- Agendas, pocket diaries, bookmarks, calendars, desk clocks;
- Subscriptions to publications;
- Diaries, fridge magnets, kit folders;
- Mouse pads, note pads, Post-it Notes, script pads;
- Office supplies, such as paperweights, pens & penholders, plastic portfolios;
- Stress/rehabilitation balls, back supports, stirrup covers and similar so-called "patient aids";
- Stationery items, such as patient appointment cards containing patient information;
- Product-bearing advertising;
- Tote bags and bags with a corporate logo (single sponsorship).

15.2.4 Each part of a multi-component service-oriented vehicle must comply with Sections 15.2.1, 15.2.2, 15.2.3 and 15.2.4.

CLINICAL EVALUATION PACKAGES ("SAMPLES")

16.1 General Principles

16.1.1 Members believe that the timely distribution of Clinical Evaluation Packages (CEPs) to Health Care Professionals as authorized by Health Canada, following the rules set out by the Food and Drugs Act and Regulations regarding samples, provides benefits to both patients and Health Care Professionals. When used appropriately members believe CEPs are an important tool for Health Care Professionals and provide benefit to patient health outcomes.

16.1.2 CEPs must be dispensed by Health Care Professionals only. Their main use is to, when appropriate; determine a patient's clinical response to drug therapy before a full course of therapy is prescribed.

16.2 Definition

16.2.1 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 through different methods of distribution, free of charge, for patient treatment.

16.2.2 In addition to the Food and Drugs Act and Regulations governing the manufacture, packaging, storage, and distribution of CEPs, hospital and/or institutional regulations may apply.

16.3 Distribution

16.3.1 CEPs shall only be given to authorized Health Care Professionals who have signed an order for the CEP. The order for the CEP must be completed by the Health Care Professional before being passed on to authorized company personnel (such as the Member's Sales Representative or another authorized agent of the Member or third party).

16.3.2 An essential part of the CEP service involves providing the Health Care Professionals with prescribing information. This information is to be shared with his/her patient. Members 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.

16.3.3 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 CEPs are supplied, the goods must be documented on a separate "NO CHARGE" invoice. CEPs should be labeled "Not for resale".

16.3.4 Giving out CEPs at convention/clinic displays, business meeting and event or at learning programs is prohibited.

16.3.5 Members should ensure they have a policy in place to comply with all applicable requirements set out in the Food and Drugs Act and Regulations. Prior to distribution, Members must take reasonable measures to prevent the theft, sale and/or inappropriate distribution of CEPs.

16.4 Storage

16.4.1 Prior to distribution, CEPs must be stored in locked cabinets, storage areas, or rooms which are only accessible to Member Sales Representatives or other authorized personnel, and must be stored in conditions that will maintain their stability, integrity and effectiveness.

16.5 Disposal

16.5.1 Members are responsible for ensuring that all excess and/or expired CEPs of their own products are returned to the Member' storehouse or head office, or an authorized third party, for appropriate disposal.

16.6 Inventory

16.6.1 Members should have adequate systems of control and accountability for CEPs provided to Health Care Professionals and must ensure that a complete and accurate inventory of all CEPs held by Member Representatives or other authorized personnel is conducted on an annual basis by an appropriate individual assigned by the Member, and not by the representative who holds the CEPs.

MARKET RESEARCH

17.1 General Principles

17.1.1 Market research links the consumer, customer and public to the marketer through the gathering of anonymized respondent information – for the sole purpose of pointing out and defining marketing opportunities and issues; generating, refining, and evaluating marketing programs; monitoring marketing performance; identifying patient and prescriber needs and improving understanding of the marketing process.

17.1.2 Market research details the information needed to address these issues, designs the method(s) by which anonymized respondent information is to be collected, manages and/or implements the data collection process, analyzes the collective results, and communicates the findings and their implications.

17.1.3 This section applies to market research carried out within the framework of various activities including quantitative and/or qualitative studies such as: individual and group interviews, ethnographic research, and patient level information.

17.2 Standards

17.2.1 Market research should always be conducted for the sole purpose of collecting legitimate market information, following proper and accepted principles guiding the collection and dissemination of market research information and the treatment of the respondent(s) and the information they provide.

17.2.2 The market research questionnaire or program should not be designed in a manner that could be interpreted as leading to a specific response or product conclusion. More specifically, the market research program should not be designed to sway the opinion(s) of the participant(s) directly or indirectly about Member Prescription Medicines and should not be used to convince or promote the use of Member Prescription Medicines, as a disguise for selling or developing sales contacts, or as a substitute or disguise for clinical research.

17.2.3 The number of experts surveyed should be reasonable in light of the total number of Health Care Professionals part of that specialty.

17.2.4 Member companies should take appropriate steps to ensure Health Care Professionals do not leave any market research meetings with any kind of promotional material.

17.2.5 The purpose of a market research program and, if applicable, the use of recording devices and presence of research 'Viewers' must be made clear to participant(s) at the start of the interview. The research Viewer(s)'s identity must remain anonymous to participants to preserve respondent objectivity. Due to confidentiality of respondents, "Viewers" may not include Member sales representatives or any other field-based personnel who have contact with and the ability to influence respondents/participants.

17.2.6 Even when a consent form is signed, the confidentiality and anonymity of participant(s) and their individual responses must be preserved to the fullest extent possible. The identity of the participant(s) must not be revealed for purposes of promoting Member Prescription Medicines to them in the future. The purpose of the market research as well as the way the responses (individually or aggregated) will be transmitted to the Member should be transparently stated in the consent form.

17.2.7 Direct contact with the participant(s) in the market research project, in which the identity of the sponsoring company is intentionally masked, should be limited to marketing research personnel only with no Member sales representatives' influence or involvement. There should be no follow-up by sales representatives or staff derived specifically from these market research projects.

17.2.8 Honoraria offered to Health Care Professionals who gather or provide market research information should be based on industry accepted rates for market research activities and should be similar to (and not higher than) their usual rate of compensation.

17.2.9 Members are committed to separating market research from other types of activities unrelated to the sole purpose of gathering of legitimate market information.

POST REGISTRATION CLINICAL STUDIES

18.1 Definition

18.1.1 A "post registration clinical study" (for the purposes of this Section 18, "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 Prescription Medicine.

18.1.2 A study with the underlying purpose to familiarize Health Care Professionals and/or patients with the use of a prescription medicine or encourage its prescription, often referred to as "seeding" or "experience" trials, is not an acceptable post registration clinical study.

18.2 General Principle

18.2.1 The main purpose of a study will be to answer scientific question(s) 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 Prescription Medicine.

18.3 Standards

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

18.3.2 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.

18.3.3 The Member 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 Health Care Professional or the subject as part of the clinical study, it is the Member'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. Members 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.

Sales representatives' and their direct supervisors' 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.

18.3.4 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.

18.3.5 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).

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

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

18.3.8 Researchers' compensation must reflect costs incurred in conducting the study, such as professional fees, salaries of study staff, and laboratory tests. Compensation 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 Members and Health Care Professionals for the study must be clearly defined, constitute part of the investigator and Member files, and any remuneration must be reasonable and reflect the fair market value of the services provided.

18.3.9 Payment to researchers must not be based on continuing administration of the Prescription Medicine under study to patients after the researcher has completed the study protocol.

18.3.10 Material provided to the Health Care Professionals 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.

18.3.11 Any correspondence or presentations to investigative staff during the course of a study should have no product or branding claims.

18.3.12 If a product is supplied to the Health Care Professionals to use in the study, it should be labelled "For clinical trial use only".

18.3.13 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 Member personnel from the medical/scientific departments and, if warranted, other Member employees who have an essential role in the functioning of the study from the design, conduct or management perspective.

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

18.3.15 Section 6 should be referred to with regards to social interaction incidental to such meetings.

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

ENFORCEMENT

19.1 Each Member Must Monitor its Compliance with the Code

19.1.1 Each Member should have:

- An employee or agent responsible for overseeing the compliance with the Code.
- This person should:
    - Ensure that Member employees are trained on the requirements of the Code; and
    - Implement a monitoring program to ensure the Member's adherence to the Code.

19.1.2 On an annual basis, an authorized representative of each Member must confirm to Innovative Medicines Canada in writing that they have policies and procedures in place to facilitate ongoing compliance with the Code.

19.2 How to File a Complaint

Complaints about any breach of the Code including a breach of the Guiding Principles must be sent in writing to the Industry Practices Review Committee (IPRC) at Innovative Medicines Canada's Ottawa office. The IPRC will decide on the validity of the complaint. Written complaints must be filed within 120 days of the event(s) giving rise to the complaint(s) or of the date when the events became known to, or reasonably ought to have been known to, the complainant. Complaints falling outside of this time frame will not be considered by the IPRC.

19.3 Response Time

19.3.1 The IPRC usually convenes on a quarterly basis and will review the complaint and any response and decide on the validity of the complaint at the first meeting following the receipt of the complaint.

19.4 Valid Complaint

19.4.1 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 twenty (20) business days following the meeting. The IPRC decision will be written and provided to the parties involved no later than three (3) business days following the decision.

19.5 Invalid Complaint

Should the IPRC determine the complaint is invalid; the IPRC will reject the complaint with a written explanation.

19.6 Violations

19.6.1 Each unique violation as determined by the IPRC shall normally count as one (1) violation. However, it is within the discretion of the IPRC for the purpose of setting penalties per Section 19.7 to count any violation as two (2) violations, if it determines that such violation was a deliberate contravention. A violation will be deemed to be a deliberate contravention of the Code when it is clearly not in compliance with one or more of the Guiding Principles.

19.7 Penalties

19.7.1 The following penalties apply to Members that violate the Code during a twelve (12)-month calendar year:

a. Upon first violation: Publication of the infraction on the Innovative Medicines Canada website and a fine of $25,000;

b. Upon second violation: Publication of the infraction on the Innovative Medicines Canada website and a fine of $50,000;

c. Upon third violation: Publication of the infraction on the Innovative Medicines Canada website, a fine of $75,000, and the Chief Executive Officer (CEO) of the Member must appear before the Innovative Medicines Canada 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;

d. Each additional violation after a third one: Publication of the infraction on the Innovative Medicines Canada website and a fine of $100,000; and all postings will remain on the website for twenty-four (24) months from the date of the final decision.

19.8 Compliance Statement

19.8.1 Within ninety (90) days of the final decision date with respect to any Code infraction, the Member must confirm in writing to Innovative Medicines Canada that it has halted the activity or otherwise addressed the issue that caused the infraction. A copy of this compliance statement will be posted on the Innovative Medicines Canada website with the relevant decision of the IPRC.

19.8.2 In the event that Innovative Medicines Canada determines that the Member has not complied with this requirement, the Member will be deemed to have deliberately contravened one of the Guiding Principles, and the penalties set out in Section 19.7 will apply.

19.8.3 In exceptional circumstances, a Member, acting in good faith, may believe that more than ninety (90) days will be required to comply with this Section 19.8. In this case, the Member must file a written extension request with Innovative Medicines Canada within ten (10) days of the decision date, providing a detailed supporting rationale for the request, and an estimate of the time required. Innovative Medicines Canada will forward the extension request to the IPRC who will evaluate the extension request and make a recommendation to the Innovative Medicines Canada Executive Committee (EC) within ten (10) days of its receipt. The EC, in its sole discretion, may elect to grant such an extension to the Member.

19.9 Repeat Offenders/Recidivists

19.9.1 In the event that any Member has five (5) or more violations in one calendar year, or has two successive calendar years with at least three violations in each calendar year: The Innovative Medicines Canada Executive Committee (EC) will convene and place the Member with such violations on a twelve (12)-month probationary period; the 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 twelve (12)-month period, beginning at the next scheduled BoD meeting, regarding remediation actions taken;
- Innovative Medicines Canada will communicate in writing with the CEO and Chair of the Board of the Member and its parent company, informing them of the situation.

19.9.2 The Member will communicate its probationary status to all Health Care Professionals, Stakeholders and Governments 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 Innovative Medicines Canada. In the event that a Member is expelled from Innovative Medicines Canada, notice of such shall be posted on the Innovative Medicines Canada website.

19.10 Deliberate Contravention

19.10.1 Any action found to deliberately contravene any of the Guiding Principles may be a just cause for expulsion. The BoD has discretion to determine if any other action is just cause for expulsion.

19.11 Urgent Hearing

19.11.1 The Executive Committee shall hold a hearing when the matter is concerning a deliberate contravention of one of the Guiding Principles.

19.12 Membership Reapplication

19.12.1 An ex-Member may reapply for membership after a twenty-four (24)-month period upon providing evidence of its improved compliance environment. The readmission is subject to the BoD's approval.

19.13 Appeal

Should the complainant or the respondent not accept the IPRC decision, either party involved in the complaint has recourse to an appeal.

19.13.1 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 Innovative Medicines Canada; and
- A panel of three adjudicators:
    - To which the parties have agreed upon;
    - The adjudicators 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 adjudicators within five (5) business days of the nomination of any arbitrator, the President of Innovative Medicines Canada shall appoint them at his/her own discretion.

19.13.2 The notice of appeal must be sent in writing to the IPRC, at Innovative Medicines Canada's offices in Ottawa, within ten (10) business days of receipt of the IPRC's decision.

19.13.3 The appeal must be heard within four (4) weeks of the nomination of the adjudication panel, or within a reasonable timeline.

19.13.4 The panel will render its decision, when possible, no later than twenty (20) business days following the hearing.

19.13.5 The panel decision will be provided in writing to the parties, when possible, within twenty (20) business days following the hearing.

19.13.6 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).

19.14 Cost

19.14.1 Any costs incurred by any of the parties (Members) involved in the appeal must be paid by them, respectively;

19.14.2 Costs resulting from the appointment and participation of the arbitrators' panel will be paid by the party which loses the appeal; and

19.14.3 When a complaint is found to be invalid by the IPRC, the complainant will pay any cost incurred to convene the IPRC.

19.15 No Appeal is Filed

19.15.1 If no appeal is filed in the timeframe described in Section 19.13.2, 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 Innovative Medicines Canada.

19.16 IPRC Members

19.16.1 Permanent members and one or 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;
- A representative as appointed by Innovative Medicines Canada's President; and
- Innovative Medicines Canada's General Counsel.

19.16.2 Additional members can be:

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

19.17 Applicable laws

All proceedings under Section 19 shall be governed by and construed in accordance with the laws of the Provinces and Canada, without regard to principles of conflicts of law.

ANNEX A

INNOVATIVE MEDICINES CANADA GUIDELINES FOR TRANSPARENCY IN STAKEHOLDER FUNDING

Principles

The innovative pharmaceutical industry believes in the value of strong, effective relationships with stakeholders across a range of sectors. Stakeholder groups, be they patient groups, health charities, professional associations, academics or the business community, each work to meet the needs of their respective constituencies by providing information, education, and discussion of issues important to Canadians. Given the range of issues in common, it is natural that the pharmaceutical industry and stakeholder groups should work together. However, the industry also recognizes that there exists the potential for conflict of interest, either real or perceived, in the relationship. For this reason, the innovative pharmaceutical industry is committed to engaging in relationships that are transparent, trustworthy and credible. Member companies therefore agree to adhere to the following principles:

1. The health and wellbeing of patients and all Canadians is the first priority of the innovative pharmaceutical industry.
2. The independence and integrity of stakeholders, in terms of their operations, policies and activities, should be assured.
3. All interactions with stakeholders should be conducted in a manner that avoids any real or perceived conflict of interest.
4. Joint activities should be based on mutual respect and trust, with the parameters of such ventures clearly delineated.
5. Members should maintain transparent funding relationships with all stakeholder partners, and require their stakeholder partners to do likewise.
6. Clear lines of communication should be established at an early stage of any undertaking between Members and stakeholders.
7. Members should encourage stakeholders to obtain funding for their operations and activities from multiple sources.

Guidelines

The following set of Guidelines has been developed in order to bring the principles to life and to help Member companies and stakeholder groups implement them in their daily activities. Their purpose is to ensure transparency and clarity of understanding, not to inhibit or restrict partnership opportunities. The new Guidelines were implemented by Members in January 2009.

1. Projects, events or activities undertaken with stakeholders should not be used to promote specific medicines.
2. All projects, events or activities must adhere to the requirements and the spirit of the Innovative Medicines Canada Code of Ethical Practices.
3. Member companies should post on their corporate websites their commitment to engage in transparent funding practices with stakeholders.
4. Prior to providing any direct funding to stakeholders, Members should ensure that there is a clear, mutual understanding of each partner's contribution and responsibilities, via a letter of agreement or other written document, outlining parameters within which funds are to be used.
5. Members should regularly disclose, by means of their web sites and annual reports, a list of all stakeholders to which they provide direct funding.
6. Members should ensure that they are identified on materials to which they contributed financially or in kind. All Members agree to follow all Codes pertaining to patient information and patient advertising.
7. To the greatest extent practicable, a Member should not be the exclusive funder of a stakeholder organization.
8. Members should refrain from creating patient groups whose sole purpose is to further market access in an area of therapeutic interest.