2018

CODE OF ETHICAL PRACTICES

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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 dis

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 reW*nractions witSt

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.

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

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

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-

8.2.3 Meeting Location

8.2.3.1 Consultant meetings must be held in Canada. The only exception is those held in conjunction

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.

9.2.3

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

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 .31 TL27 92 re W*nBT/F25 BT*nBT/F25 W*nBT/F25 BT*nBT/F25 W*n BT/F25 Gifts, offers or enticements prohibited.

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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.

10.3.2 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 Mgh the Ca8(i)5(an)61 7

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.

PATIENT SUPPORT PROGRAMS AND MEDICAL PRACTICE ACTIVITIES

14.1 Definitions

14.1.1 Patient Support Programs

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 “pati

CLINICAL EVALUATION PACKAGES (“SAMPLES”)

16.1 General Principles

16.1.1

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

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”

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 fol 2 7926(c)-4(on)15(s)-4(i)5(der)5(ed) f4Gu6792 reW*nBT/F2 10.56

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

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

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

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: