Baker McKenzie.

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance

CANADA

Canada

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The Regulatory Framework

Introduction

The relationship between medical product manufacturers, healthcare professionals and members of the public depends on a legal and ethical framework that prioritizes the promotion of health and principled decision- making. In Canada, this legal and ethical framework consists of various statutes and regulations that define the standards of permissible medical product promotion, as well as professional and industry codes that guide the interactions between medical product manufacturers and healthcare professionals.

This chapter surveys the applicable laws and the relevant professional and industry codes, as well as ethical standards that govern healthcare professionals and medical product manufacturers and suppliers in relation to the promotion of drugs,[1] natural health products and medical devices in Canada.[2]

Government

Canada operates as a federal state with governmental powers divided between the federal government and 13 provincial/territorial governments. Government at all levels is involved in health protection and promotion, including the regulation and delivery of healthcare

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[1] The term "drugs" as used in this chapter includes biologics or any product produced through biotechnology.

[2] The information presented reflects applicable federal law and national policy, as well as the law and policy of the province of Ontario. Although the same may generally be true for other provinces and territories, Ontario will stand as a representative example, without addressing the complex web of applicable statutes, regulations and codes of conduct covering all 10 provinces and three territories of Canada.

services. National principles of health and welfare are established and administered by the federal government through the Canada Health Act.[3] Guided by the Canada Health Act, the provinces and territories have responsibility for the delivery of healthcare services within their jurisdictions. Healthcare services include primary healthcare, such as the provision (and regulation) of healthcare professionals and hospital care.

Public Healthcare

The marketing and promotion of medical products, including drugs, take place within the context of Canada's public healthcare system. The universal public healthcare system established under the Canada Health Act, known to Canadians as "Medicare," is public in that universal access to medically necessary physician and hospital services is publicly funded for all Canadians.

Access to medical products is separately funded, with both public and private insurance plans providing coverage to most (if not all) Canadians. Public drug plans are administered by the provinces and territories for seniors and those receiving social assistance; while the federal government provides coverage for First Nations, Inuit, Canadian Forces members and veterans, Royal Canadian Mounted Police members, inmates of federal penitentiaries and certain migrants. Private drug plans are provided through employer and individual plans.

It is important to recognize the nexus between commercial interest and public policy interest in order to understand the rules with respect to promoting medical products in Canada.

Medical Products

Before a discussion on permitted promotional activity can ensue, it is important to understand the medical product nomenclature that exists in Canada.

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[3] RSC 1985, c. C-6.

Health Canada is the federal department responsible for national public health in Canada. The Health Product and Food Branch is the division of Health Canada responsible for managing the health-related risks and benefits of health products and food. Oversight of its activities is delegated to various directorates. The directorates relevant to this chapter are as follows:

- The Therapeutic Products Directorate is responsible for regulating drugs and medical devices in humans pursuant to the Food and Drugs Act,[4] the Food and Drug Regulations[5] and Medical Devices Regulations.[6]

- The Biologics and Genetic Therapies Directorate is responsible for regulating biological drugs in humans, which are products derived from living sources, such as vaccines, blood-derived products, tissues and organs, disinfectants and radiopharmaceuticals, pursuant to the Food and Drugs Act and the Food and Drug Regulations.

- The Natural and Nonprescription Health Products Directorate is responsible for regulating natural health products pursuant to the Natural Health Products Regulations[7] (as well as nonprescription drugs). Natural health products include vitamin and mineral supplements and herbal products associated with therapeutic claims. Natural health products are not regulated as drugs in Canada.

[4] Food and Drugs Act, RSC 1985, c. F-27.
[5] Food and Drug Regulations, CRC, c. 870.
[6] Medical Devices Regulations, SOR/98-282.
[7] Natural Health Products Regulations, SOR/2003-196.

The Food and Drugs Act defines "drug" and "device" as follows:

- "Drug" includes any substance or mixture of substances manufactured, sold or represented for use in:
    - the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals;
    - restoring, correcting or modifying organic functions in human beings or animals; or
    - disinfection in premises in which food is manufactured, prepared or kept.[8]
- "Device" means an instrument, apparatus, contrivance or other similar article, or an *in vitro* reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in:
    - diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals;
    - restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies, in human beings or animals;
    - diagnosing pregnancy in human beings or animals;
    - caring for human beings or animals during pregnancy or at birth or after the birth of the offspring, including caring for the offspring; or
    - preventing conception in human beings or animals.

[8] Food and Drugs Act, *supra* note 4, s. 2.

However, it does not include such an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to above solely by pharmacological, immunological or metabolic means, or solely by chemical means in or on the body of a human being or animal.[9]

The Natural Health Products Regulations define "natural health product" as follows:

- "Natural health product" means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in:
    - the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
    - restoring or correcting organic functions in humans; or
    - modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.[10]

Schedule 1 of the Natural Health Products Regulations includes vitamins, minerals, amino acids, essential fatty acids, probiotics and certain organic materials and their synthetic duplicates.

Before a drug or device can be sold or advertised in Canada, it must be approved by the appropriate Directorate.[11] Before a natural health

[9] *Ibid.,* s. 2.
[10] Natural Health Products Regulations, *supra* at note 7, s. 1(1).
[11] Therapeutic Products Directorate, Health Canada: http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/tpd-dpt/index-eng.php.

product can be sold or advertised in Canada, it must be approved by the Natural and Nonprescription Health Products Directorate.[12]

Healthcare Professionals and Medical Product Manufacturers

Independent healthcare professionals and medical product manufacturers and suppliers are important partners in the healthcare system. The Canadian healthcare system relies on private industry not only to conduct the research and development necessary to manufacture new medical products, but also to inform and educate healthcare professionals about the availability and appropriate use of their products. Because direct-to-public advertising of prescription drugs is prohibited[13] in Canada under the Food and Drugs Act,[14] the relationship between manufacturers and healthcare professionals is particularly important.

In Canada there are no specific statutes that govern the promotion and marketing practices of medical product companies in terms of their interaction with healthcare institutions and professionals. However, Health Canada has released a number of guidance documents to assist both manufacturers and healthcare professionals in understanding permissible promotional activity. In turn, various professional and industry groups have established codes of conduct, guidelines and ethical standards to govern the conduct of their respective members, including interactive conduct related to the promotion of medical products. The legitimacy of any marketing and promotional activity tends to be assessed through a framework that is fact-specific and context-sensitive. In so doing, regulators must balance the competing interests underlying the promotional activity as between commercially motivated medical product manufacturers and healthcare professionals who must make treatment decisions based on objective scientific data free of commercial influence.

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[12] Natural Health Products Regulations, *supra* at note 7, s. 4(1).
[13] A limited exception was introduced in 1978 to permit the advertisement of the name, price and quantity of a prescription drug pursuant to the Food and Drug Regulations, s. C.01.044.
[14] Food and Drugs Act, *supra* note 4, s. 3.

There is, however, a significant degree of similarity and alignment in the ethical standards adopted by the various industry and healthcare professional groups. Clear common themes emerge as to the proper conduct expected of healthcare professionals and medical product manufacturers and suppliers. The purpose of this chapter is to extract from the maze of statutes, regulations, codes and guidelines those core concepts and key examples that define acceptable practices. This overview will provide the basis for a general understanding of the law and policy sufficient to guide prudent decision-making.

Restrictions Under Medical Product Advertising Law

The Food and Drugs Act strictly regulates the labeling and advertising of all medical products and prohibits misleading or deceptive practices.[15] The Food and Drugs Act defines an advertisement broadly as "any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device."[16]

It is the responsibility of all advertisers to ensure that medical product advertisements comply with the requirements of the Food and Drugs Act and the related Food and Drug Regulations,[17] Medical Devices Regulations[18] and Natural Health Products Regulations.[19] The requirements under the various regulatory regimes differ depending on the type of medical product being sold, labeled or advertised and the target audience. However, the Food and Drugs Act, the Food and Drug Regulations and the Medical Devices Regulations do not specifically address the promotion of medical products to healthcare professionals.

To guide manufacturers and healthcare practitioners, Health Canada publishes instructive policy documents in relation to the advertising of

[15] Food and Drugs Act, *supra* note 4, ss. 9 and 20.
[16] Food and Drugs Act, *supra* note 4, s. 2.
[17] Food and Drug Regulations, *supra* note 5, s. C.01.044.
[18] Medical Devices Regulations, *supra* note 6.
[19] Natural Health Product Regulations, *supra* note 7.

drug and health products, a list of which can be found on the Health Canada website.[20] One such policy document entitled "The Distinction Between Advertising and Other Activities"[21] provides guidance on the distinction between an advertisement and non-promotional information.

Specifically with respect to drugs, the promotion of prescription drugs to the general public is limited to name, price and quantity,[22] and no drug (prescription and non-prescription) may be advertised to the general public for the treatment, prevention or cure of those diseases identified in Schedule A of the Food and Drugs Act.[23] The list of diseases in Schedule A includes those which are important to public health, such as cancer, diabetes and heart disease, as well as those that are not necessarily health-related, such as baldness. Natural health products are exempt from this prohibition in Schedule A insofar as they may be advertised as a preventative of a listed disease; but not as a treatment or cure.[24]

The Food and Drug Regulations prohibit a manufacturer from selling or advertising to healthcare professionals a drug for a use other than for indications that have been approved by Health Canada. In other words, manufacturers are prohibited from promoting a drug for any off-label use.[25] Manufacturers receiving unsolicited queries regarding a product's off-label use must be careful to ensure that their responses are not interpreted by Health Canada as being for the purpose of sale or promotion of the drug for off-label use. Health Canada does not condone or authorize off-label use of drugs, primarily due to the risks associated with the lack of clinical data from formal clinical trials conducted to determine how the off-label use will affect the patient's

[20] http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/index-eng.php.
[21] Health Canada, Policy Document, issued 12 January 1996; updated August 2005: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/advert-publicit/actv_promo_vs_info-eng.pdf
[22] Food and Drug Regulations, *supra* note 5, s. C.01.044.
[23] Food and Drugs Act, *supra* note 4, s. 3(1).
[24] Natural Health Products Regulation, *supra* note 7, s. 103.2.
[25] Food and Drugs Regulations, *supra* note 5, s. C.08.002.

condition.[26] That said, prescribing professionals (e.g., physicians and dentists) are not prevented from prescribing drugs for uses other than indications for which the drug is approved.

With respect to medical devices, Class II, Class III and Class IV medical devices must be licensed by the Therapeutic Products Directorate before they can be advertised.[27] Class I devices are those that present the lowest levels of risk and do not require a license.[28]

In addition to the Food and Drugs Act and its related regulations, there are certain federal commercial and criminal laws that must be observed. For example, the Competition Act[29] prohibits misleading, deceiving or otherwise exploiting consumers, with both civil and criminal sanctions available to deter offenders.[30]

Provincial Law

As previously noted, the regulation of healthcare professionals is the responsibility of the provinces and territories. Occupations falling within the category of "healthcare professional" are defined by statute. In Ontario, the Regulated Health Professions Act[31] regulates the practice of 26 categories of healthcare professionals, including physicians, nurses, dentists and pharmacists.[32] This statute establishes a framework to ensure that regulated healthcare professionals provide healthcare services in a safe, professional and ethical manner.

The Regulated Health Professions Act delegates to the governing body of each regulated healthcare professional the authority to

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[26] Health Products and Food Branch, Health Canada, July 29, 2003, "Response to Recommendations to Health Canada of the Coroner's Jury into the Death of Ashley Marie Atkinson": http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/death-deces_atkinson-eng.php
[27] Medical Devices Regulations, *supra* note 6, s. 27.
[28] *Ibid.*, s. 6 and Schedule 1.
[29] RSC 1985, c. C-34.
[30] *Ibid.*, ss. 52 and 74.01.
[31] SO 1991, c. 18.
[32] *Ibid.*, Schedule 1.

prescribe and enforce binding codes of professional conduct.[33] These codes of conduct provide most of the specific practical guidance to healthcare professionals in their interactions with the medical products industry. For example, the Professional Misconduct Regulations[34] under the Medicine Act, 1991,[35] generally prohibit physicians from engaging in activity that is, or may be perceived to be, a conflict of interest.[36] In conjunction with certain voluntary industry and professional codes, these regulatory codes of conduct for healthcare professionals serve to define the scope of permissible marketing and promotional practices.

Restrictions Under Professional Codes of Conduct

Physicians

The Canadian Medical Association (CMA) is the largest association of physicians in Canada. It has established certain standards of ethical behavior expected of Canadian physicians.

One such set of standards is the CMA Code of Ethics,[37] which guides Canadian physicians on ethics surrounding such issues as the advertising and promotion of medical products: "Avoid promoting, as a member of the medical profession, any service (except your own) or product for personal gain."[38]

The CMA has also adopted the "Guidelines for Physicians in Interactions with Industry"[39] (the "CMA Guidelines"). The CMA Guidelines outline the principles underlying appropriate interactions between physicians and the pharmaceutical and health-related

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[33] *Ibid.*, Schedule 2.
[34] O. Reg. 856/93.
[35] Medicine Act, SO 1991, c. 30.
[36] Professional Misconduct Regulations, O. Reg. 856/93, s. 1(1).
[37] CMA's "Code of Ethics," March 2015: http://policybase.cma.ca/dbtw-wpd/PolicyPDF/PD04-06.pdf
[38] *Ibid.*, page 4
[39] CMA's "Guidelines for Physicians in Interactions with Industry", 2007: http://policybase.cma.ca/dbtw-wpd/Policypdf/PD08-01.pdf

industries. The goal of the CMA Guidelines is to ensure that this relationship maintains autonomy and places patient interests before personal consideration or profit-making. The CMA Guidelines extend to medical students and residents and cover a variety of areas, such as industry-sponsored research, continuing medical education (CME) and conflicts of interest.

As a voluntary organization, the CMA has no authority to enforce these standards. However, as a national association representing the interests of physicians, various CMA codes and standards of conduct have been used as models or adopted by provincial healthcare professional regulatory bodies, which have enforcement authority. For instance, the governing body for physicians in the province of Ontario, the College of Physicians and Surgeons of Ontario, has developed a practice guide that articulates the Ontario health profession's values and principles.[40] The practice guide contains a general section on the avoidance of conflicts of interest. The College has also adopted the CMA Guidelines in its own conflict of interest policy, recently adopted in September 2014, which governs physician interaction with industry,[41] including the promotion of medical products and services.

The CMA continually works with Canadian stakeholders to resolve discrepancies between the CMA Guidelines and pharmaceutical industry codes of conduct, especially with respect to providing physicians with such benefits as paying for travel, lodging or other personal expenses of physicians attending a CME event. The CMA regularly explores strategies for increasing awareness of its standards of conduct and to educate physicians on the importance of these standards and their underlying purpose.

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[40] College of Physicians and Surgeons of Ontario, "The Practice Guide: Medical Professionalism and College Policies," revised 2008 at: http://www.cpso.on.ca/policies/guide/default.aspx?id=1696

[41] College of Physicians and Surgeons of Ontario, Policy Statement #2-14, "Physicians' Relationships with Industry: Practice, Education and Research", September 2014: http://www.cpso.on.ca/CPSO/media/images/Policies%20and%20Publications/Rel_Industry.pdf?ext=.pdf

Pharmacists

The Canadian Pharmacists Association (CPhA) is a national association of pharmacists. Similar to the CMA, it is a voluntary organization that maintains several policy and position statements. For example, the "CPhA Position Statement on Pharmacist Prescribing"[42] underscores the principle that all decisions related to medication management must be collaborative, patient-centered and focused on addressing the healthcare needs of the patient. It is worth noting that the CPhA has formally articulated its opposition to direct-to-consumer advertising.[43]

The Canadian Society of Hospital Pharmacists (CSHP) is another voluntary national association of institution-based pharmacists, such as those that operate within hospitals and long-term care facilities.

It, too, issues policies that govern the conduct of its members."[44] Unlike the CPhA, the CSHP's policy documents are not publicly available.

On a provincial level, the governing bodies of pharmacists also maintain codes of ethics. For instance, the Ontario College of Pharmacists has adopted the "Code of Ethics,"[45] which establishes fundamental principles of ethical behavior for its members that are largely derived from the standards of conduct developed by the CPhA and CSHP.

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[42] Canadian Pharmacists Association, October 2011: http://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/PPPharmacistPrescribing.pdf and: https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/Pharmacists%20Prescribing%20in%20Canada.pdf

[43] "CPhA Position Statement on Direct-to-Consumer Advertising," September 2009: http://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/PPDirectToConsumerAdvertising.pdf

[44] See list of CSHP's publicly-accessible publications and policy documents: http://www.cshp.ca/productsServices/officialPublications/type_e.asp

[45] Ontario College of Pharmacists, published December 2015: http://www.ocpinfo.com/library/council/download/CodeofEthics2015.pdf

Pharmaceutical Companies

There are two components to the pharmaceutical industry. The first comprises research-focused pharmaceutical companies, which share the common purpose of researching and discovering innovative drugs, vaccines and treatments. Innovative Medicines Canada (IMC)[46] is a voluntary national association of more than 50 research- and development-based pharmaceutical companies of all sizes. As a member of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), IMC supports the principles of the IFPMA's "Code of Practice."[47] The Code of Practice outlines the rules and principles relating to a broad range of pharmaceutical company activities, from interacting with healthcare professionals to the contents of pharmaceutical advertisements. The IFPMA's "Code of Practice" emphasizes that the healthcare and well-being of patients must be the priority for pharmaceutical companies.

IMC also publishes its own "Code of Ethical Practices"[48] (the "IMC Code"), which sets out numerous principles and practices for the promotion of prescription pharmaceutical products dispensed for human consumption. An agreement to comply with the rules of the "Code of Ethical Practices" is a condition of IMC membership.[49]

The second segment of the pharmaceutical industry is comprised of manufacturers of subsequent entry pharmaceutical products. The Canadian Generic Pharmaceutical Association (CGPA) is a voluntary industry association that represents manufacturers and distributors of generic pharmaceutical products. The CGPA adopted the "Code of Marketing Conduct Governing the Sale of Generic Pharmaceutical

[46] IMC is the organization formerly known as Rx&D. Its name change became effective on January 4, 2016.
[47] International Federation of Pharmaceutical Manufacturers & Associations, 2012: http://www.ifpma.org/fileadmin/content/Publication/2012/IFPMA_Code_of_Practice_2012_new_logo.pdf.
[48] IMC's "Code of Ethical Practices", 2016: http://innovativemedicines.ca/ethics/code-of-ethics/
[49] *Ibid.*, page 7.

Products in Canada" (the "Code of Marketing Conduct"),[50] which describes the association's rules and principles for promoting generic medicines in Canada.

Medical Technology Industry

Canada's Medical Technology Companies (MEDEC) is the national association that was created by and for the Canadian medical technology industry. MEDEC has adopted the "MEDEC Code of Conduct on Interactions with Healthcare Professionals and Government Officials"[51] (the "MEDEC Code of Conduct"), which is directed to the promotion of ethical business practices and socially responsible conduct in the context of interactions between healthcare professionals and the Canadian medical technology industry. The MEDEC Code of Conduct addresses numerous types of interactions, such as gifts, grants, arrangements with consultants, company-sponsored product training and "value added" items in conjunction with requests for proposals.

As of 2016, a number of Canada's pharmaceutical companies were listed as "code certified" members of MEDEC. In order to achieve "code certified" status, member companies must take the MEDEC Code of Conduct training or provide evidence of their equivalent internal compliance training programs.[52]

Preclearance of Medical Product Advertising

To assist medical product manufacturers in meeting their obligations to ensure that all medical product advertising in all media is compliant with the Food and Drugs Act and related regulations, Health Canada recognizes certain entities that review and preclear advertising

[50] CGPA's "Code of Marketing Conduct", most recently updated August 21, 2013: http://www.canadiangenerics.ca/en/conduct/code_marketing_conduct.asp
[51] MEDEC's "Code of Conduct," adopted April 2015: http://c.ymcdn.com/sites/www.medec.org/resource/resmgr/Docs/2015_MEDEC_Code_of_Conduct.pdf?hhSearchTerms=%22code+and+conduct%22
[52] See the full list of MEDEC "code certified" members: http://www.medec.org/?page=CodeCertified

material before dissemination to healthcare professionals and/or the general public.[53] These Advertising Preclearance Agencies (APAs) are independent of Health Canada. However, Health Canada acts as an ex-officio observer and advisor to, and works in collaboration with, these APAs. Advertising that is approved by the APA is assigned an approval number and given the authorization to use the APA logo or seal/mark, which indicates compliance with the applicable legislation, regulations, Health Canada guidance documents and the APA's code of advertising.

Health Canada recognizes three APAs:

- Pharmaceutical Advertising Advisory Board (PAAB)
- Advertising Standards Canada (ASC)
- Extreme Reach[54] (formerly known as Mijo)

Although the APA process is not mandatory, Health Canada encourages industry sponsors to comply with the preclearance and approval mechanisms provided by these agencies. Health Canada's "Guidance Document – Health Canada and Advertising Preclearance Agencies' Roles Related to Health Product Advertising"[55] provides information about the preclearance process and Health Canada's relationship to the APAs.

Pharmaceutical Advertising Advisory Board

PAAB is the APA that preclears advertising material for prescription, non-prescription, biologics, and natural health products directed to healthcare professionals. In so doing, it ensures the advertising is

[53] Health Canada Guidance Document issued 2010: "Health Canada and Advertising Preclearance Agencies' Roles Related to Health Product Advertising".
[54] Mijo was acquired by Extreme Reach, Inc. effective February 2014.
[55] Health Canada, November 2010, available at: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/advert-publicit/pol/role_apa-pca-eng.pdf

accurate, balanced, and evidence-based.[56] While voluntary, most manufacturers take advantage of the PAAB process.[57] In fact, PAAB reviewed 7,718 new submissions in 2015.[58]

The PAAB maintains a "Code of Advertising Acceptance"[59] (the "PAAB Code") which conforms with the relevant requirements of the Food and Drugs Act, related regulations and the various guidance documents issued by Health Canada. The PAAB Code provides a comprehensive set of standards for the promotion of medical products to healthcare professionals in all media, including promotional claims, comparative claims, disclosure and presentation of scientific and statistical data, and the prescription of products.

While its primary mandate is directed to the preclearance of advertising material directed to healthcare professionals, PAAB provides an advisory service for messages directed to consumers regarding prescription drugs and biologics and on educational material discussing a medical condition or disease.

The PAAB regularly monitors medical journals, the Internet, and direct-mail/detail aid materials collected by healthcare professionals to determine whether any such advertising material has received PAAB clearance.[60] When violations of the PAAB Code are identified, PAAB sends a letter to the advertiser, seeking its cooperation to meet the Code's requirements. When appropriate, the PAAB will notify the

[56] See PAAB's "Creating Fair Balance Checklist": http://www.paab.ca/Tips_and_checklist_for_creating_and_selecting_fair_balance_(October_2015).pdf
[57] See list of PAAB clients: http://www.paab.ca/clientlist.htm
[58] "PAAB Views," PAAB newsletter, January 2016, page 3: http://us9.campaign-archive2.com/?u=039ba1341543609b6a31a37ff&id=8033f87b59
[59] PAAB's "Code of Advertising Acceptance," most recently revised July 1, 2013: http://www.paab.ca/paab-code.htm
[60] *Ibid*., s. 10.1.

advertiser's trade association and/or Health Canada for the assessment of additional penalties.[61]

PAAB also administers a complaint and appeal procedure by which allegations concerning non-compliant medical product advertising can be reviewed and resolved on an administrative basis. Health Canada will intervene when advertising that contravenes the Food and Drugs Act or related regulations may present an imminent and/or significant health hazard,[62] or when contravening advertising arises from the willful non-participation of the drug advertiser.[63]

Advertising Standards Canada and Extreme Reach

Both the ASC and Extreme Reach are APAs that review and preclear advertising material relating to non-prescription drug and natural health products directed to consumers.

In addition, and similar to the PAAB, the ASC provides an advisory service for messages directed to consumers regarding prescription drugs and biologics and on educational material discussing a medical condition or disease. The ASC has adopted a code of advertising standards, being the "Canadian Code of Advertising Standards".[64] This code is designed to ensure such advertising material maintains honesty, accuracy and fairness. A complaint procedure is also provided, with escalation to Health Canada if necessary.

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[61] "PAAB Views," PAAB newsletter, April 2012, page 4: http://www.paab.ca/resources/newsletters/PAAB%20Views%20April%202012%20E.pdf

[62] PAAB "Code of Advertising Acceptance," *supra* note 59, s. 9.9.5.

[63] Health Canada "Guidance Document – Health Canada and Advertising Preclearance Agencies' Roles Related to Health Product Advertising," *supra* note 46, s. 3.5.2.4.

[64] ASC's "Canadian Code of Advertising Standards", most recently revised August 2014: http://www.adstandards.com/en/standards/canCodeOfAdStandards.pdf

Permitted and Prohibited Practices

This section expands on the more common areas of engagement between manufacturers and healthcare practitioners on medical product promotion with a view to providing guidance on what is permitted.

Gifts, Hospitality and Entertainment

The CMA Guidelines provide that physicians should not accept personal gifts from the medical products industry.[65] However, they may accept patient teaching aids appropriate to their area of practice, provided these aids carry only the logo of the donor company and do not refer to "specific therapeutic agents, services, or other products."[66]

As mentioned above, regulations under the Medicine Act, 1991 (Ontario), deem a conflict of interest to be an act of professional misconduct.[67] Under these regulations, it is a conflict of interest for a member of the College of Physicians and Surgeons of Ontario to, among other things: (i) receive any "benefit" directly or indirectly, from a supplier who sells or otherwise supplies "medical goods or services" to his or her patients; or (ii) sells or otherwise supplies any drug, medical appliance, medical product or biological preparation to his or her patient at a profit except under exceptional circumstances, such as a medical emergency or immediate treatment need.[68]

The scope of such conflicts of interest is defined by how the regulations interpret what constitutes a "benefit" or a "medical good or service." "Benefit" is defined as any benefit, gift, advantage or emolument of any kind, whether direct or indirect. "Medical goods or services" include medical goods, appliances, materials, services and equipment, and drugs and laboratory services. It should be noted that the prohibition placed on the member of the College of Physicians and

[65] CMA's "Guidelines for Physicians in Interactions with Industry," *supra* note 39, para. 44.
[66] *Ibid*., para. 50.
[67] Professional Misconduct Regulations, *supra* note 36, s. 1(1).
[68] O. Reg. 114/94, s. 16.

Surgeons extends to a member of his or her family, or a corporation wholly, substantially, or actually owned or controlled by the member or a member of his or her family.[69]

More generally, the College of Physicians and Surgeons of Ontario has articulated the fundamental principle of its conflict of interest policies as follows: "A physician must always act in the patient's best interests. A physician's interests should not be in conflict with the patient's. Any conflicts of interest must be properly managed so as not to compromise the patient's best interests, or be avoided."[70] Based on this, it is expected that any pharmaceutical advertising that is not in the best interests of the patient will likely constitute a conflict of interest and as such, will be considered an act of professional misconduct.

Similarly, the "Code of Ethics for Members of the Ontario College of Pharmacists" provides that members of the council must not accept gifts or other benefits for services related to their profession, although they are allowed "reasonable customary hospitality" so long as they are reported to the council.[71]

On the industry side, the IMC Code provides that member companies must not offer to any healthcare professional, or to any member of a healthcare professional's clinical or administrative staff, any gift or any promotional aid, prize, reward, or any other item that is intended for personal or family benefit or pecuniary advantage. Members must ensure that the distribution of service-oriented items is not conducted for product promotional purposes.[72]

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[69] *Ibid*., s. 16.
[70] College of Physicians and Surgeons of Ontario, "Duties: To the Patient," revised 2008: http://www.cpso.on.ca/Policies-Publications/The-Practice-Guide-Medical-Professionalism-and-Col/Principles-of-Practice-and-Duties-of-Physicians/Duties-To-the-Patient/Duties-To-the-Patient-Managing-Conflicts-of-Intere
[71] Ontario College of Pharmacists, "Code of Ethics," *supra* note 45, at s. 1.2.10.
[72] IMC's "Code of Ethical Practices," *supra* note 48, at s. 15.1.3 and s. 15.1.4.

The IMC Code provides that member companies may distribute acceptable service-oriented items, defined as items having the primary goal of enhancing the healthcare professional's or patient's understanding of a condition or its treatment. Such items may bear the corporate name and logo of the donor, but must not bear the name of any brand or medicine.[73]

The IMC Code also provides that during business interactions with healthcare professionals or other stakeholders,[74] members may only provide reasonable refreshments and meals that are ancillary to the associated activity. Under no circumstances can refreshments or meals be extended to spouses or companions of healthcare professionals unless the spouse or companion is also a healthcare professional. No other form of hospitality or entertainment is to be provided, including tickets, vouchers or defraying the cost of any entertainment event. The number of attendees is limited to that which is reasonable and justifiable.[75]

The MEDEC Code of Conduct provides that companies occasionally may provide gifts to healthcare professionals. However, gifts should have a fair market value of less than CAD100, unless they are medical textbooks or anatomical models used for educational purposes. Companies may also occasionally provide healthcare professionals with branded promotional items of minimal value related to the healthcare professional's work or for the benefit of patients. No gifts of cash or cash equivalents may be given.[76]

Seminars, Conferences and Continuing Health Education

The IMC Code acknowledges that symposia, congresses and other continuing health education (CHE) programs are important ways for companies to dispense knowledge and for healthcare practitioners to

[73] *Ibid*., s. 15.1.1.
[74] "Other stakeholder" is defined to include any individual or organization impacted by the activities of a member company, *Ibid*., page 8.
[75] *Ibid*., s. 6.3.1 and s. 6.3.2.
[76] MEDEC's "Code of Conduct," *supra* note 51, page I.

share their experiences with each other.[77] The guidelines in the various professional codes of conduct distinguish between payments on behalf of those who attend the congresses and those who participate as speakers and moderators.

Member companies may provide grants and honoraria to healthcare professionals who speak at or moderate CHE programs. Such grants and honoraria cannot be extended to other healthcare professionals who attend the program or to the spouses or family members of those in attendance.

Therefore, generally speaking, travel and accommodation expenses can only be paid to speakers and moderators, not to attendees. In no case may such expenses be subsidized for the spouse and family members of any professional conference participant. Member companies should not be involved in the development of or payment for social functions conducted in conjunction with any CHE event.[78]

With respect to CHE events held outside Canada, both the supporting company and the recipient(s) of the financial support should proceed on the understanding that the ultimate objective in exposing Canadian healthcare professionals to international CHE events is improved healthcare for Canadians. In considering such requests, IMC members must adhere to the following parameters:

- The request must be made in writing and include all details of the program, as well as the proposed educational program(s) to be delivered by the returning participant, and indicate whether support has been requested from any other company for the same event.
- The member providing the support must respond to the request in writing, and explain the conditions for financial support.

[77] IMC's "Code of Ethical Practices," *supra* note 48, s. 9.1.1.
[78] *Ibid*., s. 9.2.5 and s. 9.2.7.

- The returning participant will be required to share with Canadians the benefit of knowledge gained through a written report to the supporting company, the relevant speciality society or academic institution, or through an oral presentation to healthcare professionals (such reports and presentations must acknowledge the financial support received and the company providing it).

- Support may be provided by members to a maximum of 10 healthcare professionals to any one international CHE event.[79]

The CMA Guidelines also set out principles of appropriate conduct with regards to continuing medical education (CME) and continuing professional development (CPD). Specifically, they state that the primary purpose of CME/CPD activities should be to address the educational needs of healthcare professionals in order to improve the provision of healthcare services.[80] Travel, accommodation, hospitality and social events for industry- sponsored CME/CPD activities should align with those that would normally be made without industry sponsorship. Hence, the industry sponsor should not pay for travel, lodging costs or other personal expenses of physicians.[81] The CMA also prohibits peer selling, which is the process by which a pharmaceutical or medical device manufacturer, service provider or third-party representative engages a physician to conduct a seminar that focuses on its own products and is designed to enhance the sale of those products.[82]

The MEDEC Code of Conduct provides that education and training must be given in a way that ensures the independence of healthcare professionals. Companies are required to ensure that:

- the main focus of an event is educational;

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[79] *Ibid*., s. 10.2.
[80] CMA's "Guidelines for Physicians in Interactions with Industry," *supra* note 39, para. 22.
[81] *Ibid*. at para. 32.
[82] *Ibid*. at para. 29.

- hospitality is modest;
- social and non-professional activities do not overshadow educational events;
- programs and events are conducted in appropriate locations, such as clinics, laboratories or educational facilities;
- training is conducted by qualified staff; and
- guests of healthcare professionals are not subsidized.[83]

Additionally, MEDEC member companies may provide educational grants to CHE conference sponsors if: (i) the grant is focused on scientific or educational activities; and (ii) the conference sponsor selects the program content, the participating faculty, the educational methods, the materials to be used, and the healthcare professionals who will attend. Funding may be provided to conference faculty for travel, lodging, meals and honoraria. Finally, MEDEC member companies are permitted to purchase advertisements and lease booths for CHE conference displays.[84]

Samples

The Food and Drugs Act prohibits the distribution of any drug as a sample, unless it is done under prescribed conditions to physicians, dentists, veterinary surgeons or pharmacists.[85] Under the related regulations, where one of the foregoing healthcare professionals provides a signed order to a pharmaceutical company/representative specifying the brand name, proper name or common name and quantity of a drug (other than a narcotic, a controlled drug or a new drug for which marketing authorization has not been issued), the company or representative may distribute the drug to the healthcare

[83] MEDEC's "Code of Conduct," *supra* note 51, page 4.
[84] *Ibid*., pages 4-5.
[85] Food and Drugs Act, *supra* note 4, s. 14.

professional as a sample if the drug is labeled in accordance with the regulations.[86]

The Food and Drug Regulations also mandate record-keeping requirements. Any company distributing a drug as a sample must maintain records showing the following:

- Name, address and description of each person to whom the drug is distributed
- Brand name, quantity and form of the drug distributed
- Date upon which each such distribution was made

These records and all orders received for samples must be kept for a period of at least two years from the date when the sample was provided.[87]

The CMA Guidelines provide that the distribution of samples (often referred to as "clinical evaluation packages" in the industry and professional codes) should not involve any form of material gain for the physician or for the practice with which he or she is associated. Physicians who accept samples and other healthcare products are responsible for ensuring their age-related quality and security. They are also responsible for the proper disposal of unused samples.[88]

The Canadian Society of Hospital Pharmacists generally discourages the use of samples in hospitals. However, in the event samples are brought in, CSHP mandates that they be controlled, stored and distributed by the hospital's pharmacy service.[89] All samples should be listed on an invoice and authorized for acceptance by the director

[86] Food and Drug Regulations, *supra* note 5, s. C.01.048.
[87] *Ibid*., s. C.01.049.
[88] CMA's "Guidelines for Physicians in Interactions with Industry," *supra* note 39, paras. 42-43.
[89] Canadian Society of Hospital Pharmacists, "Guidelines for Drug-use Control", last accessed 29 March 2016: http://www.cshp.ca/dms/dmsView/1_1_DrugUseControl-25July08-CAL.pdf

of the hospital's pharmacy in order to allow the monitoring of expiry dates and lot numbers. Samples are to be delivered directly to the hospital pharmacy from the company or company representative to ensure product integrity. Any current or previous use of samples must not influence dispensing decisions.

The IMC Code provides that only healthcare professionals may dispense samples.[90] In addition to the legal requirements in the Food and Drugs Act and associated Food and Drug Regulations, the IMC Code indicates that the following rules also apply to its members:

- Distribution:[91]: Samples shall only be given to authorized healthcare professionals who have filled out a request form for the sample. The request form must be fully completed by the healthcare professional before being passed on to authorized company personnel (such as the company representative or another designated employee) for signature. An essential part of the sample service involves providing the healthcare professional with prescribing information. This information is to be shared with his or her patient. The company should also provide full prescribing information on the sample 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.

  All free goods given to a healthcare professional as part of an order must be included on an invoice. If no order is made when the free goods are supplied, the goods must be documented on a separate 'no charge' invoice.

  Members should implement a policy to comply with all applicable requirements set out in the Food and Drugs Act and

[90] IMC's "Code of Ethical Practices," *supra* at note 48, at s. 16.1.2.
[91] *Ibid*., s. 16.3.

related regulations, and measures to prevent the theft, sale or inappropriate distribution of samples.

It is not appropriate to give out samples at conventions.

- Storage:[92] All samples must be stored in locked cabinets, storage areas or rooms that are only accessible to company representatives or other authorized people. Companies must direct their employees to store samples in conditions where the stability, integrity and effectiveness of the samples will be maintained.

- Disposal:[93] Companies are responsible for making sure that all excess and/or expired samples of their own manufacture are returned to the company's storehouse or head office, or an authorized third party, for appropriate disposal.

- Inventory:[94] Companies must make sure that a complete and accurate inventory of all samples held by company representatives be conducted at least once a year. Inventory will be taken by an independent agent hired by the company, not by the representative who holds the samples.

Sanctions and Liability

Liability Under the Food and Drugs Act

Health Canada administers the Food and Drugs Act and its regulations, establishes certain minimum standards to be met in advertising, and may intervene in relation to contraventions.[95]

A manufacturer or supplier of medical products that contravenes any provision of the Food and Drugs Act or its regulations, including those provisions relating to advertising and labeling, may be found guilty of

[92] *Ibid*., s. 16.4.
[93] *Ibid*., s. 16.5.
[94] *Ibid*., s. 16.6.
[95] *Ibid*., s. 22, 23 and s. 30(1)(p).

an offense and liable on conviction to a fine of up to CAD5,000, and to imprisonment for a term of up to three years.[96] In the event that the selling and promotion of a medical product presents a serious or imminent risk of injury to health, the fine that may be ordered increases significantly to up to CAD5 million, along with a maximum term of imprisonment of two years.[97]

Professional and Industry Codes

If a member of a regulated health profession under the Regulated Health Professions Act is found to have committed an act of professional misconduct (which includes conflict of interest), one or more of the following orders may be made:[98]

- Revocation of the member's certificate of registration
- Suspension of the member's certificate of registration for a specified period of time
- Imposition of specified terms, conditions and limitations on the member's certificate of registration for a specified or indefinite period of time
- Requiring the member to appear for reprimand
- Requiring the member to pay a fine of not more than CAD35,000

Having investigated the question to the extent possible, it would appear to be highly unusual for a physician to be disciplined by the College for contravening the CMA Guidelines.[99]

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[96] Food and Drugs Act, *supra* note 4, s. 31(b).
[97] *Ibid*., s. 21.3 and s. 31.2
[98] Regulated Health Professions Act, 1991, *supra* note 31, Sched 2, s. 51(2).
[99] See e.g. the College of Physicians and Surgeons of Ontario's disciplinary decisions at: http://www.cpso.on.ca/whatsnew/news-releases

Although the IMC is a voluntary association, it requires its members to uphold the Code of Marketing Practices, and also urges all companies that market or sell pharmaceuticals but who are not members of IMC, to follow the code as well. The principles set out in the IMC Code must be adhered to as a condition of membership to the IMC. Complaints received by the IMC Industry Practices Committee in Ottawa (usually from physicians) will be investigated. A list of the complaints filed since 2008 is available online, along with the committee's decision in each case.[100] The committee's written decision is delivered to all parties involved in the matter.

The following penalties apply to companies that violate the IMC Code during any 12-month period:[101]

- First violation: Publication of infraction on the IMC website and a fine of CAD25,000
- Second violation: Same as for the first violation, plus a fine of CAD50,000
- Third violation: Same as for the second violation, plus a fine of CAD75,000, and the CEO of the company must appear before IMC's board of directors in order to provide a detailed explanation of the violations and a comprehensive written action plan to ensure remediation
- Additional violation: Publication of the infraction on the IMC website and a fine of CAD100,000

There are also provisions in the IMC Code that deal with repeat offenders and deliberate contraventions.[102]

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[100] IMC, "Complaints 2008-2015," last updated April 2015: http://innovativemedicines.ca/ethics/complaints/
[101] IMC's "Code of Ethical Practices," *supra* note 48, at s. 19.7.
[102] *Ibid.*, s. 19.9 and s. 19.10.

Any party involved in the complaint has recourse to an appeal process. If no appeal is filed in the time provided, the Committee's decision will be considered final and the company must adhere to the decision as a condition of continued membership in the IMC.[103]

Liability Under Criminal Law

Professional misconduct and breach of the applicable codes of conduct for healthcare professionals and for members of the IMC are not grounds for criminal sanction. Only where corruption, surreptitious distribution, fraud, secret commissions in agency relationships, or acceptance of illicit inducements is involved would criminal liability be possible.

Public Corruption and Bribery

No level of government in Canada is generally in the business of buying or selling medical products. As mentioned above, the majority of hospitals in Canada are public hospitals in the sense that they are government-funded, but they are neither owned nor controlled by the government. Furthermore, the activities of hospital professionals and staff are regulated but not controlled by government. Most physicians in Canada are in private practice and serve patients in hospitals on the basis of accreditation and "hospital privilege" access to the facilities. Hence, most physicians employed in hospitals are essentially independent contractors and those staff physicians directly employed by these hospitals would not be considered "government employees." On this basis, Canadian anti-bribery and anti-corruption laws would have no application.

However, there are some psychiatric facilities and military hospitals that are government-owned, and physicians employed by these facilities may be considered public officials for purposes of Canadian anti-bribery and anti- corruption statutes. As well, physicians employed by federal or Ontario government entities, such as the Ontario Ministry of Health and Long-Term Care, would be considered

[103] *Ibid.*, s. 19.13.

government employees. In relative proportions, there are only a small number of healthcare institutions and professionals that would be included in this category. To the extent that Canada's public anti-bribery and anti-corruption laws may apply to this group of healthcare institutions and professionals, the following elements should be noted in passing:

- Federal government procurement policy prohibits the payment of business and sales representatives on a commission basis for being instrumental in the obtaining of a government contract.

- The federal government also has various codes of ethics pertaining to government procurement, which include policies with respect to gifts and entertainment that appear to be consistent with those referenced in the industry codes identified above. In this regard, Canadian law is also expressed in the Criminal Code bribery provisions ("frauds upon the government"), as well as certain government codes and guidelines that restrict the giving of payments, gifts, hospitality and other benefits to Canadian government officials.

- Individuals who lobby the federal government, or who lobby provincial government officials in the provinces of British Columbia, Alberta, Manitoba, Ontario, Quebec, Nova Scotia or Newfoundland and Labrador must register under the Lobbying Act (Canada) and/or the applicable provincial lobbyists registration acts, as appropriate. In this regard, by way of example, "public office holder" is broadly defined in the Ontario statute[104] to include virtually everyone working

[104] Ontario's Lobbyists Registration Act, 1998, SO 1998, c. 27, Schedule (the "LRA") came into effect on 15 January 1999. The LRA is very similar to Canada's federal lobbyists registration legislation that was enacted in 1989. The stated intention of the Ontario government is to create a public record of paid lobbyists to ensure that the process of lobbying government is kept open and transparent, and that the public interest is protected from undue influence. Any individual or organization that lobbies

within the Ontario government, whether elected, appointed or employed, although it does not include Crown corporation employees (unless appointed by the provincial Cabinet), judges, justices of the peace, officers of the Legislative Assembly (e.g., Ombudsman, Information & Privacy Commissioner), or broader public sector entities such as hospitals, universities and local government institutions. Failure to register could result in a fine of up to CAD25,000.

- Additionally, in Quebec, legislation came into force in 2015 that applies to all public contracts and creates a voluntary reimbursement program allowing enterprises to reimburse (and the government to recover) amounts improperly paid by public bodies as a result of fraud or fraudulent activities.[105]

- The Canadian Criminal Code[106] contains a number of offenses dealing with bribery under the title "Corruption and Disobedience" in sections 119 to 130, including "frauds on the government," which is aimed, in part, at what is known as influence peddling.[107] These anti-bribery provisions are rather broad and make it an offense for anyone dealing with the government to confer any advantage or benefit of any kind on an employee or official of the government with respect to those dealings. If a company representative were to commit bribery, the Criminal Code provisions with respect to "aiding and abetting" means it is conceivable that the firm involved could also be found guilty under these broad anti-bribery provisions. The US federal Foreign Corruption Practices

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a "public office holder" is required to register with the Office of the Integrity Commissioner.

[105] Voluntary Reimbursement Program (An Act to ensure mainly the recovery of amounts obtained as a result of fraud or fraudulent tactics in connection with public contracts), CQLR. c. R-2.2.0.0.3, r. 1. The legislation was restricted initially to contracts in the construction industry, but ultimately was expanded to apply to any category of public contracts (including the health and social services sector).

[106] RSC 1985, c. C-34.

[107] Section 121.

Act[108] (FCPA) may apply to corrupt practices that involve government-employed healthcare professionals. The FCPA prohibits US and foreign issuers from bribing public officials outside the US and applies to any person pursuing a bribery arrangement with a foreign official while in American territory.

Private Bribery

There are no specific recourses available to a person who has been a victim of corruption, but Canadian courts have had to consider the tort of unlawful interference with economic interests. With regard to existing contracts, there is some case law supporting the proposition that a party, such as a business competitor, who induces a breach of a rival's contract by convincing a third party to do an unlawful act, may be liable for the loss or damage that the rival sustains. Tort liability could also arise in a case of interference short of a breach. With regard to new contracts, the law is less clear.

The tort of unlawful interference is discussed in the Ontario case of *Future Health Inc. v. Cividino*,[109] where the court dismissed a motion to strike a statement of claim for failure to disclose a reasonable cause of action. In Quebec, the Civil Code contains provisions that could be invoked to claim damages. In conclusion, in both the common law provinces and Quebec, possible remedies exist for those "whose rights and interests are affected by corruption".[110] [111]

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[108] 15 USC § 78dd-1 *et seq*.
[109] (1999), 41 O.R. (3d) 275 (Ont. Gen. Div.). The tort has also been referred to as "interference with a trade or business by unlawful means," "intentional interference with economic relations," "causing loss by unlawful means," "causing loss by unlawful means," or simply the "unlawful means" tort, as noted by the Supreme Court of Canada in *A.I. Enterprises Ltd. v. Bram Enterprises Ltd*. [2014] SCC 12.
[110] All provinces and territories in Canada are common law jurisdictions, with the exception of Quebec, which is a civil law jurisdiction.
[111] The Supreme Court of Canada noted in the *A.I. Enterprises Ltd*. decision (*supra* note 110) that Quebec civil law takes a "fundamentally different approach" and goes further than the Anglo-Canadian "unlawful means" tort because under civil law, liability may be imposed for conduct that is "otherwise lawful" but is done with the

Contracts with Healthcare Professionals and Medical Institutions

It would be a conflict of interest and professional misconduct for a Canadian healthcare professional to receive a commission or referral fee from a medical products manufacturer or supplier for the referral of patients, or to sell or otherwise supply any medical product to a patient at a profit.

In addition to their altruistic public welfare value, continuing medical education programs and research sponsorship clearly constitute promotional activities. Educational grants and sponsorships are a fact of life in an environment of increasing financial strain on the Canadian public healthcare system. The specific by-laws and policies of each individual hospital or educational institution must be considered in terms of the acceptable standards of conduct. Each such institution can be expected to have a policy in place with respect to sponsorship and external funding. Such policies may indicate that there is to be no real or implied obligation to promote or purchase a product manufactured by the company providing funding, and that the grant must not influence therapeutic decision making.

Although the regulatory and ethical environment applicable to clinical trials is beyond the scope of this chapter, many of the principles in the various codes of conduct reviewed in relation to advertising and promotion are repeated with respect to clinical trials and, in fact, clinical trials may be considered a preliminary form of promoting medical products to the healthcare profession.

Relevant to this consideration is a certain heightened sensitivity over conflict of interest concerns involving the nexus between Canadian hospitals and medical product manufacturers following a well-publicized case involving an Ontario hospital, one of its physicians involved in clinical research, and the pharmaceutical company

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intent to injure the plaintiff or in a manner inconsistent with the social ends of that right (based on the "abuse of rights" doctrine).

responsible for the drug research in question. In 1996, the drug company threatened the physician with legal action if she published research findings unfavorable to the company's product that she had been studying. The case involved important issues of research ethics and academic freedom that attracted national and international attention. The Report of the Committee of Inquiry into this case, initially published in 2001, found that the company should not have attempted to impede the physician from informing patients, regulators and the scientific community of the risks that she had identified regarding the drug in question. The committee recommended that companies should not attempt to suppress or control results, and that all research hospitals should have in place a policy − and measures to ensure its implementation − that prohibits agreements, contracts, or protocols that have clauses that restrict communication of risks identified in research projects, particularly clinical trials. Research hospitals were advised to react strongly in support of their clinical researchers if any sponsor threatens the researchers' independence or academic freedom, in order to fulfil their responsibility to protect the safety of their patients.

The fall-out from this case has resulted in Canadian publicly funded institutions (hospitals and universities in particular) addressing and containing, in their own policies, the "demand-side" problems and risks associated with increasing reliance on outside resources of financial support.

Conclusions and Recommendations

As with many jurisdictions, the healthcare system in Canada is facing review and reform in the face of growing financial strain and public concern. In an era of decreased government funding and the corresponding opportunity for private participation, commercial concerns are therefore very much part of the social welfare debate and in the public view. With heightened sensitivities, bad behavior can garner significant public attention. Ultimately, significant incidents can generate intensification of regulatory oversight with increased administrative costs to enterprise. The damage to brand value and

reputation can be much more immediate. Public perception is therefore the principal forum of accountability to keep in mind when interpreting the various laws and guidelines surveyed in this chapter.

This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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