FREQUENTLY ASKED QUESTIONS

THE MEDTECH CANADA CODE OF CONDUCT ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS, HEALTHCARE INSTITUTIONS AND GOVERNMENT OFFICIALS

Why is there a Medtech Canada Code of Conduct?

Given the importance of fairness, transparency, integrity and accountability in the medical technology industry, Medtech Canada's Board of Directors wants to ensure that our member Companies are provided clear guidelines to govern their interactions with Healthcare Professionals, Healthcare Institutions and Government Officials. Collectively, our member Companies and Board support adhering to ethical business practices and the principles in the Medtech Canada Code of Conduct for Interactions with Healthcare Professionals, Healthcare Institutions and Government Officials.

Why has Medtech Canada updated its Code of Conduct?

The Medtech Canada Code of Conduct is designed to be a "living document" that is regularly reviewed and updated by the Medtech Canada Code of Conduct Steering Committee. The code's most recent update modernizes the Code, addresses some frequently asked questions from Medtech Canada member Companies, brings the Code in line with current compliance standards, generally aligns the Code with AdvaMed and MedTech Europe codes of conduct, addresses issues of concerns raised by compliance authorities and adds specificity and clarity where needed.

Why is Medtech Canada's Code of Conduct different than AdvaMed's Code of Ethics and MedTech Europe's Code of Business Practice?

Medtech Canada's Code of Conduct is generally consistent with other similar codes in the industry including the AdvaMed Code of Ethics and the MedTech Europe Code of Business Practice. A Canada specific Code is required, however, to recognize and address Canada's distinct healthcare technology laws, guidelines and regulations, as well as Canadian compliance industry standards. Companies doing business across multiple jurisdictions are encouraged to follow all applicable codes and, in the unlikely event of conflicting guidance between codes, adhere to the highest applicable standard.

Is the Medtech Canada Code of Conduct binding?

Medtech Canada's Code of Conduct applies to all Medtech Canada member Companies, and a commitment to comply with the Code is a condition of our member Companies' Medtech Canada certification. Non-member companies are encouraged to use the Code as guidance in their interactions with HCP, HCI and GO. The Code is consistent with current compliance industry standards and applicable laws, and all companies are encouraged to include an asessment of Code compliance in their internal compliance monitoring and auditing processes.

Does the Medtech Canada Code of conduct provide for legal rights and remedies, or offer legal advice?

No. The Code is intended to provide Medtech Canada member Companies with guidelines to follow in order to facilitate ethical behavior, and is not intended to be, nor should it be, construed as legal advice. The Code does not define or

Medtech Canada

405 The West Mall, Suite 900 Toronto, Ontario M9C 5J1
t: 416.620.1915 toll free: 1-866-586-3332
www.medtechcanada.org

create legal rights or remedies. Companies have an independent responsibility to determine whether their interactions with Healthcare Professionals (HCP), Healthcare Institutions (HCI) and Government Officials (GO) comply with applicable laws and regulations.

What interactions are governed by the Code?

The Code governs Medtech Canada's member Companies' interactions with Healthcare Professionals, Healthcare Institutions and Government Officials.

The term "Healthcare Professionals" is broadly defined with the intent to encompass anyone who purchases, leases, recommends, uses or arranges the purchase, lease or use of Medical Technology in Canada. This would include, for example and without limitation, physicians, nurses, nurse practitioners, dentists, audiologists, chiropodists, optometrists and other healthcare professionals.

The term "Healthcare Institutions" is also broadly defined to include any institution, corporation, government body, agency or committee and any other organization involved in the purchase or other acquisition, supply, distribution, assessment, funding or recommendation of Medical Technology. This would include, for example and without limitation, hospitals, healthcare clinics, group purchasing organizations, shared service organizations.

The term "Government Officials:" means any official or employee of a government agency or governmental department, political party or public organization. This includes officers and employees of governmment-owned companies, or companies substantially controlled by government.

The HCP, HCI and GO interactions governed by the Code include:

- Medical Technology Training and Education programs;
- Sponsorships of third-party educational conferences;
- Sales, promotional and business meetings;
- Consulting arrangements with HCPs;
- Value-based arrangements;
- Gifts;
- Grants and charitable donations;
- Procurement and contracting principles;
- Entertainment and recreation;
- Meals, refreshments and travel;
- Medical Technology evaluations;
- On-Site product demonstrations;
- Company site visits; and
- Third party intermediaries.

What about other interactions not addressed by the Code?

The Medtech Canada Code of Conduct does not provide guidance on every type of interaction, but rather focuses on the most common types of interactions and those which may give rise to potential breaches of ethics or integrity. Where a situation is not specifically addressed in the Code or by applicable law or regulation, Companies should adhere to commonly accepted ethical business practices of the highest standard and practice ethical and responsible conduct.

What are the guidelines for training and education?

Medtech Canada recognizes that its member Companies play an essential role in Canada's healthcare system by providing HCP, HCI or GO with Medical Technology Education and Training. When providing training and/or education, Companies should ensure that:

- The primary purpose of the event is to address *bona fide* education and/or training needs. Activities primarily promotional in nature are not considered *bona fide* educational/training activities.
- Meals and refreshments should be modest in value.
- Programs and events should be conducted in appropriate learning settings. Companies should consider virtual training andeducation where practicable.
- Qualified staff should provide the training.
- Companies may pay for reasonable travel, lodging and meals/refreshment incurred by attending HCPs, provided they are modest in value and subordinate to the education/training.
- Guests of Healthcare Professionals are not subsidized.

What are the guidelines for sponsorship of third-party conferences?

The following principles govern sponsorships of third-party conferences:

- Companies should only sponsor conferences which have a *bona fide* educational or scientific purpose. Sponsorship of events such as entertainment galas, or other non-educational / scientific events, is not appropriate.
- A Company's decision to sponsor a third-party educational conference may be made with the input from sales and marketing and may take into consideration the potential sales and marketing opportunities stemming from the conference. However, the decision to sponsor a conference should never be made to reward past purchases or as an unlawful, undue or improper inducement for future business.
- Sponsorships should always be given to the conference organizer or to an HCI to support their representatives' attendance at the conference, but never to an individual HCP or GO. The conference's organizer or HCI should at all times remain free to independently select attemnding HCP, HCI or GO.
- Sponsorship funding can be used towards the conference's overall costs, or to support the reasonable honoraria, travel, lodging, meals and refreshments for conference attendees.
- The conference's organizer should remain free to independently select program content, faculty, educational methods and materials.
- Companies may sponsor games of chance or sweepstakes, purchase advertisements, lease booth space, sponsor satellite symposiums, hold demonstrations or make presentations at the conference, provided all of these activities are consistent with the overall educational or scientific nature of the conference.

What are the guidelines for meetings with HCPs, HCIs and GOs?

Companies may conduct sales, promotional and other business meetings with HCP, HCI or GO to discuss, for example, product features, contract negotiations and sales terms. Participating at these meetings must not impede on the HCP, HCI or GOs ability to maintain autonomy or independence. Companies may pay for modest meals and refreshments for HCP, HCI, or GOs attending meetings. Meetings should be held in an environment that is conducive to the exchange of business information.

Can Companies offer HCPs and GOs meals and refresments?

Yes. Companies may pay for modest and reasonable meals and refrreshments to HCPs and GOs when the hospitality is part of a *bona fide* exchange of scientific, educational or business information. The setting and location for the hospitality must be conducive to business and, meals and refresments should only be offered to those attending the meeting or event for legitimate reasons (no guests). Companies should also consider adopting controls around the provision of alcohol.

What about entertainment?

No. It is never appropriate for Companies to provide or pay for any kind of entertainment of HCPs, HCIs or GOs, including without limitation attendance at sporting or music events, golf outings, golf tournaments, etc.

Can companies pay HCPs for consulting services?

Yes. Companies may retain HCPs for consulting services including acting as a key opinion leader, serving on advisory boards, consulting on research projects, or presenting at Company-sponsored training and product collaboration sessions. It is appropriate for Companies to compensate HCPs for these services, provided the HCP is permitted to accept compensation under their professional guidelines, and further provided the compensation is reasonable and no more than fair market value. HCP consulting arrangements should:

- Be in writing, specifying services and compensation provided, and signed by the parties.
- Where compensation is provided, it should be of no more than the fair market value for services provided, as established by objective calculation practices.
- Be entered into only where a legitimate need and purpose for the services is identified in advance.
- The HCP should be selected based on their qualifications and expertise to address the identified purpose, and never as a reward for past purchases or as an unlawful, undue or improper inducement for future business.
- Company-sponsored meals, refreshments and meeting venues occurring in conjunction with the consulting services should be modest in value and subordinate in time and focus to the primary purpose of the meeting.
- Companies may pay for reasonable and actual expenses incurred by consultants including reasonable and actual travel, modest meals or lodging costs.
- Where the HCP is engaged for research services, there should be a written research agreement and/or protocol.

Can a company give gifts to a Healthcare Professional?

Except in very few well defined situations, Companies must not provide gifts to Healthcare Professionals, Healthcare Institutions or Government Officials. The only acceptable gifts are those that are occasional in nature, and which relate to the HCPs practice, benefit patients or serve a genuine educational function. Examples of gifts allowed are medical textbooks or surgical and anatomical models. Any such gift must not exceed a fair market value of $100 CDN for any one instance.

It is not appropriate for Companies to:

- Give any branded promotional items (e.g., pens, notepads, mugs);
- Give any gifts that are in the form of cash or cash equivalents (e.g., gift certificates);
- Give gifts of a personal nature (e.g., gifts for marriage, birth, birthday, anniversary or retirement), save and except in the event of death, where a Company may send flowers or make a donation of not more than $100 CDN.

All gifts should be recorded and given without the expectation or reciprocity or value exchange. Gifts should never be given in whole or in part as a reward for past purchases or as an unlawful, undue or improper influence for future business.

What about grants and other charitable donations?

Companies may make donations for legitimate charitable purpose, such as supporting independent medical research, education or improved healthcare delivery. All grants and charitable donations must be made following an objective decision process, considering only the charitable purpose, without consideration or input from sales and marketing, and without considering the value or volume of purchases made by, or anticipated from, the recipient. Grants and charitable donations must never be made as a reward for past sales or on the condition, even implied, that business or sales will be awarded in return.

Companies should also consider the timing of any grant or charitable donations. Avoid making grants or charitable donations where there are proximate or ongoing tender or contract negotiations with the recipient, to avoid the appearance of undue, improper or unlawful inducement.

Grants and donations can only be made to organizations, and never to individual HCPs or GOs. All grants and charitable donations should be documented in writing and recorded on the Company's books and records.

See the Medtech Canada Code of Conduct for additional guidance re educational grants, fellowship grants, research grants and charitable donations to registered charities.

What are the guidelines for medical technology evaluations?

Companies may provide an HCP, HCI or GO with a medical technology, free of charge, for a limited evaluation trial period where:

- the purpose of the evaluation is truly to provide the HCP, HCI or GO the opportunity to evaluate a medical technology for which they do not have previous experience and/or where a trial is needed to ensure the Medical Technology meets requirements;
- the length of the evaluation period is defined at the outset and limited to a reasonable evaluation period;
- the arrangement is documented in writing, including the reason and duration of the trial.

Under no circumstances should a free trial evaluation be granted with the intention to unlawfully, unduly or improperly influence the HCP, HCI or GO.

What about product demonstrations?

Companies may provide product demonstrations, provided the medical technology remains in the control of the Company throughout the demonstration and is removed from the site at the conclusion of the demonstration. Companies should consider virtual demonstrations, where practicable. Demonstration arrangements should be documented in writing.

Where a visit to the Company's facilities is necessary, the Company may fund reasonable travel and hospitality expenses for the attending HCPs and GOs, provided the hospitality is modest in value and subordinate to the purpose of the site visit. Whenever possible, site visits should occur in Canada. Companies should only fund expenses for attendees who have a *bona fide* professional interest in the medical technology (no guests).

Are value added requests for proposals and tenders unlawful?

It is not unlawful for HCIs to request, and for Companies to offer, "value added" items as part of a procurement process. Such "value-adds" could include, for example, rebates, discounts, training or research grants. All value-adds should be:

- clearly and transparently defined and documented;
- directly related to the medical technology being procured;
- measurable and quantifiable and not unrestricted;
- of a fair market value which is proportionally lower than the overall value of the transaction.

Value-adds should never be offered as an improper, undue or unlawful inducement.

What principles govern a Company's use of third-party intermediaries?

Companies may use Third Party Intermediaries (TPI) such as distributors, sales agents, wholesalers, and brokers. In so doing, Companies should perform regular and ongoing due diligence review of the TPI to ensure that the TPIs activities are compliant with applicable laws and the Code of Conduct.

Is it a Company's responsibility to ensure HCPs, HCIs and GOs are following and complying with the various laws, regulations and professional standards that govern the HCPs, HCIs and GOs, respectively?

No. Companies are responsible to ensure that they are complying with the various laws, regulations and professional standards, including this Code of conduct, that govern and apply to the Companies. Similarly, HCPs, HCIs and GOs have their own responsibility to ensure that they are complying with the various laws, regulations and professional standards that apply to them. For example, HCPs, HCIs, and GOs are responsible to only accept hospitality if and as permitted within their own professional guidelines and applicable laws. HCPs, HCIs and GOs are also responsible to ensure that they abide by procurement-based policies and rules that require them to make independent decisions regarding Medical Technology. To be clear, while HCPs, HCIs and GOs are the ones ultimately responsible to ensure they comply with the applicable laws, regulations and professional standards that apply to them, Companies should never encourage, condone or knowingly enter into a transaction which they know is contrary to an HCP, HCI, or GO applicable law, regulation or professional standard.

What happens if a Medtech Canada member Company breaches the Code of Conduct?

Medtech Canada does not actively govern or audit compliance with the Code. Rather, all Comnpanies have an independent obligation to ascertain that their interactions with HCPs, HCIs, and GOs comply with applicable laws and regulations, and with the Medtech Canada Code of Conduct for "Code Certified" Medtech Canada member Companies. Companies are encouraged to report potential violations of the Code to Medtech Canada's President & CEO. Suspected violations will be reviewed by the Medtech Canada Code of Conduct Violations Review Committee. The Medtech Canada President & CEO and/or Violations Review Committee Chair may also act as an intermediary between member Companies to address and resolve disputes involving Code interpretation.

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