

Medtech Canada Code of Conduct

For Interactions with Healthcare Professionals (HCP), Healthcare Institutions (HCI) and Government Officials (GO)



1 The Goal of The Medtech Canada Code of Conduct

- 1.1 Medtech Canada is dedicated to advancing healthcare through innovative Medical Technology. Medtech Canada believes that fair and equal access to high quality, cost-effective Medical Technology is paramount to the improvement of patient care and delivery of a patient-centered, safe, accessible, innovative and sustainable healthcare system.
- 1.2 In pursuing this mission, Medtech Canada member Companies recognize that adherence to ethical standards and compliance with applicable laws is critical to the Canadian Medical Technology industry's ability to continue to offer innovative Medical Technology and improve patient care in collaboration with HCP, HCI and GO. Medtech Canada member Companies are committed to comply with applicable laws and regulatory requirements (including without limitation all applicable Health Canada regulations and directives such as the Health Canada rules governing the promotion of unlicensed products or promotion of unauthorized/off-label use) and general principles of fairness, transparency and integrity in their interactions with HCP, HCI and GO.
- 1.3 Companies should follow ethical business practices and responsible industry conduct in all their interactions with HCP, HCI and GO.
- 1.4 Companies should also respect the obligation of HCP, HCI and GO to make independent decisions regarding Medical Technology. Medtech Canada and its member Companies support and respect the guidelines and policies established by professional societies or organizations that outline the obligations of the profession and will respect these rules and guidelines while interacting with the HCP, HCI and GO.
- 1.5 The Medtech Canada Code of Conduct is a "living" document, regularly reviewed by the Medtech Canada Code of Conduct Committee to ensure the Code is aligned with current industry standards, business environment and applicable laws. The Code recognizes the changing business environment in Canada and globally. It also recognizes that healthcare regimes are governed by different laws, policies, and practices. The Medtech Canada Code of Conduct represents a solid framework for the Canadian marketplace.
- 1.6 All capitalized terms in this Code of Conduct are defined in the Glossary.

2 Scope of The Medtech Canada Code of Conduct

- 2.1 This Code is intended to govern Medtech Canada member Companies' interactions with HCP, HCI, and GO and includes, but is not limited to, Company interactions with those individuals or entities (such as group purchasing organizations, shared service organizations, or other HCI related entities) that purchase, lease, recommend, use, train, arrange for the purchase or lease of, or prescribe Medical Technology in Canada.

There are many forms of interactions between Companies and HCP, HCI, and GO that help to advance medical science or improve patient care, including:

- 2.1.1. **Advancement of Medical Technology.** Developing cutting-edge Medical Technology and improving existing Medical Technology by collaborative processes between Companies and HCP, HCI and GO. Innovation and creativity are essential to the development and evolution of Medical



Technology, often occurring outside the laboratories of Medical Technology Companies. Heart valves, orthopaedic implants, cardiac rhythm devices, surgical tools and infusion pumps, digital solutions and robotics are just a few examples of the array of complex Medical Technology developed through research collaborations and consulting relationships between HCP, HCI, GO and Companies.

2.1.2. Safe and Effective Use of Medical Technology. The safe and effective use of Medical Technology often requires Companies to offer HCP, HCI and GO appropriate Education, Training, service and technical support.

2.1.3. Research and Education. Companies' support of bona fide medical research, Education and enhancement of professional skills serves patient safety and increases access to new Medical Technology.

2.2 Medtech Canada recognizes that Companies may interact with HCP, HCI, or GO for many bona fide objectives other than selling, leasing, recommending, arranging for the sale or lease of, or prescribing Medical Technology and that some of these relationships are not addressed in this Code. Any interpretation of the provisions of this Code, as well as Companies' interactions with HCP, HCI, or GO not specifically addressed in this Code, should be made considering the following principle: Companies shall follow ethical business practices and responsible industry conduct and shall not use any unlawful, undue or improper inducement to sell, lease, recommend, or arrange for the sale, lease, or prescription of their Medical Technology.

3

Compliance with the Medtech Canada Code of Conduct

The Medtech Canada Code of Conduct applies to all Medtech Canada member Companies. Non-member companies may use the Medtech Canada Code as guidance in their interactions with HCP, HCI, or GO.

All companies are strongly encouraged to adopt this Code and to implement an effective compliance program – one which includes policies and procedures that foster compliance with the Code with respect to their interactions with HCP, HCI, or GO. The main intent of a compliance program is to ensure that there is not any unlawful, undue or improper influence on a sale or transaction with HCP, HCI, or GO.

Companies should follow the following three fundamental questions and seven elements of an effective compliance program, appropriately tailored for each Company, namely:

Three fundamental questions for an effective compliance program:

1. Is the corporation's compliance program well designed?
2. Is the program being applied earnestly and in good faith? In other words, is the program being implemented effectively?
3. Does the corporation's compliance program work in practice?

Seven elements of an effective compliance program:

- implementing written policies and procedures;
- designating a compliance officer and compliance committee;
- conducting effective training and education;
- developing effective lines of communication (including an anonymous reporting function);
- conducting internal monitoring and auditing;
- enforcing standards through well-publicized disciplinary guidelines; and
- responding promptly to detected problems and undertaking corrective action.

Companies are encouraged to include an assessment of Code compliance in their internal compliance monitoring and auditing process.

3.1 Code Certification

Medtech Canada will publish the names of those Companies who adopt the Code and become "Code Certified". To obtain certification, Companies will need to either complete training available through Medtech Canada or provide evidence of their own equivalent internal compliance training programs. In addition, each Company will need to certify in writing that they agree to follow the Code and have delivered Code compliance training to all of their commercial personnel. This certification must be signed off at the executive level within each Company and reissued on an annual basis to maintain certification.

Companies who are “Code Certified” will be allowed to use the Medtech Canada Code of Conduct logo when responding to customer procurement requests. Medtech Canada will encourage HCP, HCI, and GO and other customers generally to look for the Medtech Canada certification when reviewing procurement response submissions.

3.2 *Inter-Company Disputes*

Any Medtech Canada member Company disputes outside the scope of the Code of Conduct, including but not limited to compliance with any legislation or directive which is not within the jurisdiction of the Medtech Canada Violations Review Committee, should be resolved between the Medtech Canada member Companies themselves or through Health Canada, the Competition Bureau, Advertising Standards Canada, or other avenues, in each as may be applicable. The Medtech Canada CEO can be asked to assist with these discussions with a view to help resolving them between Medtech Canada member Companies.

Companies are encouraged to report potential violations of the Code of Conduct to the Medtech Canada CEO for investigation and resolution. Suspected violations of the Code may also be reported to the Medtech Canada Violations Review Committee. The primary role of the Violations Review Committee is to eliminate confusion to Code interpretation and ensure a fair and level playing field among Companies. The Violations Review Committee’s jurisdiction applies to complaints of suspected violations of the Code of Conduct.

4

Company-Conducted Product Training and Education Programs

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. Historically, Companies and HCP, HCI or GO have worked collaboratively in providing Education and Training on Medical Technology to improve the health and safety of patients and Medical Technology end users.

4.1 When providing these Medical Technology Training and Education, Companies should adhere to the following:

- Companies should ensure that the primary purpose of the program is to address the bona fide Educational and/or Training needs of the HCP, HCI and GO. If meals and refreshments are provided, they should be modest in value and subordinate to the Training and Education. Activities primarily promotional in nature should not be considered as bona fide Educational/Training programs.
- Companies should consider whether the Educational or Training program can be effectively held in a virtual manner rather than in-person.
- Educational and Training programs and events should be conducted in clinical, laboratory, educational, conference or other appropriate settings including the Company’s own facilities or commercially available meeting facilities that are conducive to effective transmission of knowledge. Where possible, programs requiring “hands-on” Training in medical procedures should be held at Training facilities, medical institutions, laboratories or other appropriate facilities. The Training staff should have the proper qualifications and expertise to conduct such Training.
- Companies may pay for reasonable travel, lodging (should an overnight stay be required), meals and refreshment costs incurred by attending HCP, HCI and GO, provided they are modest in value and the recipient is permitted to accept the hospitality within their professional guidelines and applicable laws.
- Companies are not permitted to facilitate or pay for the meals, refreshments, travel, lodging or other expenses of guests of HCP, HCI and GO or for any other person who does not have a bona fide professional interest in the Education and Training being provided at the meeting.

5

Sponsorship of Third-Party Educational Conferences

It is appropriate for Companies to sponsor bona fide independent, educational, scientific or policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective healthcare. These typically include conferences facilitated or organized by national, regional or specialty medical associations or societies, or conferences facilitated or organized by accredited Continuing Medical Education providers.

Unlike Grants and Charitable Donations decisions, which must be made based on an objective decision process without the input, control or influence from the Company’s sales and marketing departments, a Company’s decision to sponsor a Third-Party Educational Conference may be made with the input from sales and marketing departments and may take into consideration the potential sales and marketing opportunities stemming from the Third-Party Educational Conference. However, a Company’s decision to sponsor a Third-Party



Educational Conference should never be made to reward past purchases or as an unlawful, undue or improper inducement for future business. For clarity, a Company's decision to sponsor a Third-Party Educational Conference should be made based on objective criteria that does not take into account the value or volume of purchases made by, or anticipated from, the recipient of the sponsorship or the conference attendees.

Companies may support Third Party Educational Conferences in various ways:

5.1 Sponsoring the Conference

Companies may Sponsor Third Party Educational Conferences when the event is primarily dedicated to promoting objective scientific and Educational activities and discourse. Such Sponsorships can be provided to the Third-Party Educational Conference organizer or to an HCI to support their representatives (which may include HCP or GO) attendance at the Third-Party Educational Conference. In all cases, the recipient of the Company's Sponsorship shall remain free to independently select the attending HCI, HCP or GO. Such Sponsorships should be paid only to support Third Party Educational Conferences (or attendance at Third Party Educational Conferences) with a bona fide Educational purpose or function. Sponsorships also should be consistent with relevant guidelines established by professional societies or organizations. The Third-Party Educational Conference organizer should be responsible for, and control the selection of, program content, faculty, Educational methods and materials without influence from the Company Sponsoring the conference.

5.2 No Direct Support of HCP or GO

Companies may not provide direct financial support to individual HCP or GO for their attendance or professional development at Third-Party Educational Conferences. Any Sponsorship of Third-Party Educational Conferences must be directed to the conference organizer or to an HCI, but not to an individual HCP or GO.

5.3 Sponsoring Meals and Refreshments at the Conference

Companies may provide funding to the conference organizer to support the conference's meals and refreshments. Also, Companies themselves may provide meals and refreshments for HCP, HCI and GO attendees, but only if it is provided in a manner that is also consistent with these Code of Conduct guidelines (modest in value, subordinate to the overall Educational component of the conference, etc.) and applicable laws.

5.4 Sponsoring Conference Faculty Presenter Expenses

Companies may provide funding to the conference organizer to support the Reasonable honoraria, travel, lodging and modest meals or refreshments for HCP, HCI and GO who are bona fide conference faculty members and presenters at the conference.

5.5 Sponsoring Satellite Symposiums at the Conference

Companies may Sponsor Satellite Symposiums at Third- Party Educational Conferences and provide presentations on Medical Technology and related matters that are consistent with the overall content of the conference, provided that all information presented is fair, balanced and scientifically rigorous. Companies may determine the content of these Satellite Symposiums based on the Company's bona fide business needs and Companies may also be responsible for the faculty selection for these satellite symposiums. Company support for such satellite symposium events must be transparently disclosed in all materials relating to the satellite event.

5.6 Advertisements and Demonstrations at the Conference

Companies may purchase advertisements and lease booth space for Company displays advertisements and demonstrations at Third-Party Educational Conferences.

5.7 Sponsoring Conference Contests and Sweepstakes

Companies may also Sponsor games of chance such as sweepstakes or draws, or mixed chance and skill at the Third-Party Educational Conference, provided they comply with applicable laws and the Medtech Canada Code of Conduct (including the section on Gifts). Any prize sponsored or offered by the Company must not exceed the limits noted in the Gifts Section of this Code.

6

Sales, Promotional and Business Meetings

It is appropriate for Companies to conduct sales, promotional and other business meetings with HCP, HCI or GO to discuss, for example, Medical Technology features, contract negotiations and sales terms, insofar as the relationship does not impede on the HCP, HCI or GO's ability to maintain professional autonomy and independence. Such meetings should occur at or close to the HCP, HCI or GO place of business. It is appropriate for Companies to pay for occasional modest meals and refreshments for HCP, HCI or GO in the context of a business meeting and in an environment that is conducive to the exchange of business or Medical Technology information.

Where plant tours or demonstrations of non-portable Medical Technology are necessary, it is appropriate for Companies to pay for Reasonable travel costs of attending HCI, HCP or GO. However, it is not appropriate

to facilitate or pay for meals, refreshments, travel, lodging or other expenses of guests of HCl, HCP or GO or any other person who does not have a bona fide professional interest in the business or Medical Technology information being shared at the meeting.

7 Arrangements with Consultants

Many HCP serve as Consultants to Companies providing valuable bona fide Consulting services, including acting as key opinion leaders, participation on advisory boards, speaking or presenting at Company-Conducted Medical Technology Training and Educational Programs and other similar collaboration and consulting opportunities. In such cases, it is appropriate to provide the HCP with Reasonable compensation for performing these Consulting services, provided the HCP is permitted to accept the compensation within their professional guidelines and under applicable laws and further provided the compensation does not exceed fair market value.

The following factors support the existence of a bona fide Consulting arrangement between Companies and HCP:

- All consultancy agreements should have full transparency and the HCP should be required to notify their employer of the arrangement and any compensation related thereto.
- The HCP must be permitted to accept the compensation within their professional guidelines and under applicable laws. Of note, GO are generally not permitted to accept any compensation from Companies for Consulting or any other service, and, for this reason, Consulting arrangements are generally restricted to those with HCP.
- Consulting arrangements should be written, signed by the parties and specify all services to be provided and compensation to be paid.
- Compensation paid to the HCP should be no more than fair market value as established by appropriate calculation practices for the services provided.
- Consulting agreements should be entered into only where a documented *bona fide* need and purpose for the consulting services is identified in advance.
- The selection of the HCP Consultant should be based on the HCP's qualifications and expertise to address the identified purpose and duly vetted. An HCP Consultant should not be selected in whole or in part as a reward for past purchases or as an unlawful, undue or improper inducement for future business. Selection of the HCP Consultant should not be related to the volume or value of business generated by the HCP Consultant or any of its affiliated HCl.
- Company-Sponsored meals, refreshments and meeting venues that occur in conjunction with a Consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting.
- Companies may pay for Reasonable and actual expenses incurred by HCP Consultants in carrying out the subject of the consulting arrangement, including Reasonable and actual travel, modest meals and lodging costs incurred by the HCP Consultant attending meetings with, or on behalf of, Companies.
- When a Company contracts with an HCP for research services, there should be a written research agreement and/or protocol.

8 Value-Based Arrangements

Medtech Canada acknowledges that the Canadian healthcare system is transitioning from a fee-for-Medical Technology model to a value-based model. Value-based arrangements may include results-based, outcomes-based or performance-based arrangements. Value-based arrangements may also involve payment for a "bundled" group of Medical Technology and various types of interactions with HCl, HCP and GO. The guidelines in this Code should be applied to the development and delivery of any such value-based arrangements, and Companies should also adhere to all applicable laws and the general principles of fairness, transparency and integrity in their interactions with HCP, HCl and GO relating to such value-based arrangements.

9 Gifts

Except in very few well defined situations below, Companies must not provide gifts to HCP, HCl or GO.

The only acceptable gifts that can be provided are those that are occasional in nature, and which relate to the HCP, HCl or GO's practice, benefit healthcare patients or serve a genuine Educational function. Some examples of acceptable occasional Educational related gifts are surgical and anatomical models. Any such occasional Educational related gifts from a Company may not exceed a value of \$100 CDN for any one instance.



Companies may not provide any branded promotional items (e.g., pens, notepads, mugs) to HCI, HCP or GO. Gifts must also never be given in the form of cash or cash equivalents (i.e., gift cards or gift certificates).

All gifts given to HCP, HCI or GO must be recorded accurately (including recipient name, amount and frequency) and must be always provided in connection with a bona fide business relationship, without the expectation of reciprocity or value exchange. For clarity, gifts should never be given to HCI, HCP or GO in whole or in part as a reward for past purchases or as an unlawful, undue or improper inducement for future business.

Gifts to HCP, HCI or GO must never be of a personal nature. It is not considered appropriate to give gifts to an HCP, HCI or GO for their significant life events such as a marriage, birth or birthday, anniversary, or retirement. However, in the case of a death, each Company may make its own determination as to the appropriateness of sending flowers or making a donation subject to a maximum value limit of \$100 CDN or less.

10 Grants and Charitable Donations

Companies may make Grants and Charitable Donations to HCIs under certain conditions.

It is never appropriate for Companies to provide Grants or Charitable Donations for the purpose of improperly, unduly or unlawfully inducing the HCP, HCI or GO to purchase, lease, recommend, or use the Company's Medical Technology. All Grant and Charitable Donation decisions must always be made based on objective criteria that does not take into account the value or volume of purchases made by, or anticipated from, the HCP, HCI or GO. Grants and Charitable Donations must never be made 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 Donation. Companies should avoid making Grants or Charitable Donations when there are proximate or ongoing tender proceedings with the HCP, HCI or GO. To avoid any appearance of undue, improper or unlawful influence, a reasonable "cooling off" period should pass after the completion of tender proceedings before engaging in any discussions regarding Grants or Charitable Donations.

It is not allowable to provide a Grant or Charitable Donation directly to an individual HCP or GO. All grants and donations must be provided to an HCI.

In addition, Grant and Charitable Donation decisions should be made following an objective decision process, without the input, control or influence of the Company's sales and marketing departments. Where possible, Grant and Charitable Donation decisions should be vetted by the Company's compliance or legal department, or other department independent of sales and marketing.

All Grants and Charitable Donations should be appropriately documented and recorded on the Company's books and records, including recipient name, amount and frequency.

Companies should implement appropriate measures to ensure that Grants and Charitable Donations are not, and do not have the appearance of being, an undue, improper, or unlawful influence on any HCP, HCI or GO.

10.1 Educational Grants

Educational grants may be provided to HCI in support of bona fide Continuing Medical Education programs, patient or public Education or Training.

While general conditions may be tied to the Educational Grant (such as the Company requesting that the Grant be used for Education or Training in a particular field), the recipient of the Educational Grant must retain control of the content, materials, overall budget, and selection of HCP or GO receiving all or part of the Educational Grant.

Educational Grants can never be provided directly to an individual HCP or GO. Rather, Educational Grants should be provided to the HCI, who may then determine the appropriate HCP or GO recipients for the Educational Grant.

Educational grants can be monetary or in kind (i.e., the grant of Medical Technology) to be used for Educational or Training purposes.

10.2 Fellowship Grants

A fellowship Grant is a Grant that will be used by the HCI for partial payment or full payment of a fellow's salary or related expenses. Companies may consider fellowship Grants where the request has been made by the HCI without the control or influence of the Company and where the fellowship Grant is assessed on its own independent scientific or Educational merit. The HCI must remain responsible to select the fellow and the fellow must at all times work under the control and direction of the HCI.

A HCI must submit their request for a fellowship Grant to the Company with the following supporting documentation:

- A detailed request letter, fully detailing the department and work the fellow will be undertaking, and

confirming the departmental academic fund details to establish that fund is set up as an independent entity for the purpose of funding academic Education; and

- After funding has been established, a CV, including Educational details of the chosen fellow.

Any request for fellowship Grants must be assessed, reviewed, and approved through an independent non-commercial department of the Company, separate from sales and marketing, and without any influence, review or input from the Company's sales and marketing personnel. There shall be no consideration of the HCl, or related HCP or GO's past or future sales in evaluating the request for a fellowship Grant, to avoid any appearance of improper, undue or unlawful inducement.

10.3 Research Grants

Research grants may be provided to support bona fide medical research for the advancement of medical science or Medical Technology, or the improvement of healthcare services or the increased patient access to Medical Technology. Research Grants can be monetary or in kind (e.g., granting of Medical Technology for research purposes).

Research grants must be tied to specific, measurable and well-defined objectives and milestones as well as reporting obligations to the donor organization to confirm appropriate Grant use as per the applicable objectives and milestones. Research Grants may not be unrestricted, and the amount provided as Research Grant from the Company cannot materially exceed the benefits and deliverables the Company will receive from the Research collaboration.

Research Grants should be appropriately documented and recorded on the Company's books and records.

10.4 Charitable Donations

Companies may make monetary or in kind (e.g., donations of Medical Technology) donations for charitable or philanthropic purposes.

Charitable Donations should be made only to registered charitable organizations and never to individual HCP or GO. Recipient organizations may include hospital registered charitable foundations but do not include organizations that are not registered as a charity under applicable tax laws.

Charitable Donations of Medical Technology intended for clinical use are not allowable except where the donation is intended to support a humanitarian mission/disaster relief effort organized by the charitable organization.

Charitable Donations should not be made in response to a request by an individual HCP or GO unless the HCP or GO is an officer or employee of the registered charitable organization and submits a written request for the donation on behalf of the registered charitable organization

11 Procurement and Contracting Principles

11.1 General Principles

Medtech Canada is committed to ensuring fairness, transparency, accountability and supporting ethical and lawful behavior in interactions between Companies and HCP, HCl, GO and procurement organizations. As such, all Companies shall conduct business in a manner that embodies integrity and maintains public trust in the Medical Technology industry while delivering value and innovation for Canadians.

11.2 Contracts

Companies will ensure that their contracts, including those that result as part of a request for proposals, or other request for information or tender process, follow all applicable industry best practices, including Medtech Canada's updated position paper "Publication of Contract Values in Canada" and applicable codes and laws.

11.3 Value-Adds, Rebates and Discounts

It is not unlawful for HCl to request, or for Companies to offer, Value-Adds, such as rebates, discounts, Training or Research Grants as part of the procurement process.

However, Medtech Canada does not consider all value-add requests and offerings as procurement best practice. Value-Adds should:

1. never be solicited or offered as an improper, undue or unlawful inducement;
2. be compliant with the Medtech Canada Code of Conduct, Canada's anti-bribery and anti-corruption laws and each Company's own code of conduct and ethics;
3. not promote an anti-competitive environment in any way;
4. be clearly and transparently defined and documented in the procurement documentation (i.e., in the HCl's request for proposals, request for information or request for tenders, in the Company's



- propose or response, and in the resulting contract and supporting documents, all as applicable);
5. be directly related to the Medical Technology being procured;
6. be measurable and quantifiable and not be unrestricted;
7. be of fair market value which is proportionally lower than the overall value of the transaction, so as to not be considered or perceived as an improper, undue or unlawful inducement.

To ensure a fair and equitable procurement regime, Value-Adds should not be a mandatory requirement of any competitive procurement process. When a competitive procurement process contains a request for Value-Adds, the offer of any Value-Adds should be documented separately from the Medical Technology offer, and the evaluation grids should balance the influence of the Value-Add in the overall evaluation.

12 Entertainment and Recreation

It is never appropriate for Companies to provide or pay for any kind of Entertainment of HCP, HCI or GO (including without limitation attendance at sporting or entertainment or music events, golf outings, golf tournaments, etc.) regardless of whether the HCP, HCI or GO is a Company Sponsored Consultant, speaker or otherwise.

13 Meals and Travel

Modest and Reasonable meals, refreshments and travel may be provided to HCP, HCI or GO when part of a bona fide exchange of scientific, Educational or business information.

The time, duration of meals and refreshments, and the venue in which they are provided should always be Reasonable and subordinate to the business purpose. The setting and location of any hospitality must be conducive to the bona fide exchange of scientific, Educational or business information.

It is inappropriate for Companies to provide hospitality for an HCP or GO unless that HCP or GO has attended the relevant meeting and has a bona fide professional interest in the scientific, Educational or business information being shared. For example, it would be inappropriate for Companies to provide meals or refreshments to HCP or GO who are not present at the meeting, and who instead “dine and dash”.

Companies should consider adopting controls around the provision of alcohol to HCPs and GOs and at Company hosted programs and meetings. For example, Companies should consider adopting per-person drink limits, per-drink spend limits, limitations on the type of alcohol permitted, or disallow alcohol at certain events.

Modest travel expenses are generally defined as economy class with exceptions permissible only for bona fide reasons. It is not appropriate to provide meals or travel to spouses or guests of HCP, HCI or GO or for any other person without a bona fide professional interest in the event.

14 Medical Technology Evaluations

Evaluations are defined as situations where Companies provide HCP, HCI or GO with Medical Technology for use for a limited time trial period, free of charge.

In accordance with procurement policies or guidelines of the Healthcare Professional’s organization, Companies may provide products to HCP, HCI or GO at no charge, as part of the sales and customer evaluation processes provided:

- the purpose of the evaluation is truly to provide the HCP, HCI or GO with the opportunity to evaluate a Medical Technology for which the HCP, HCI or GO does not have previous experience and/or requires a trial period to ensure that the Medical Technology meets the HCP, HCI or GO requirements;
- the length of the trial/evaluation loan must be defined at the outset and limited to a reasonable evaluation period; and
- the arrangement must be documented in writing between the institution and the Company stating the duration and subject of the evaluation, as well as its purpose.

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

15 On-Site Product Demonstrations

On-site demonstrations are situations where Companies attend an HCP, HCI or GO location to demonstrate the use and features of the Company's Medical Technology.

The Medical Technology must remain in the control of the Company over the course of the demonstration. The Company must also assess if providing an on-site demonstration is appropriate in each circumstance and consider providing virtual demonstrations where practicable.

Prior to the start of the on-site demonstration, the arrangement must be documented in writing between the HCP, HCI or GO and the Company which documentation must contain the details and purpose of the demonstration, including the duration of the demonstration, the Medical Technology being demonstrated and the scope of the on-site demonstration.

Upon the conclusion of the demonstration, the Medical Technology should be removed by the Company or stored at the HCI location in a manner so that it cannot be utilized without the presence of the Company, acknowledging that consumables may have been depleted as part of the demonstration and therefore unable to be removed. No usable Medical Technology (consumables or otherwise) should be left on site at the end of the demonstration.

16 Company Site Visits

Where HCP, HCI or GO visits to a Company's clinical or manufacturing sites are necessary for the HCP, HCI or GO to evaluate the Company's Medical Technology, Companies may fund Reasonable expenses which are in line with this Code of Conduct under the following conditions:

- Whenever possible Site Visits should occur in Canada.
- Companies should fund expenses only for attendees with a *bona fide* professional interest in the Medical Technology.
- All meals, refreshments and travels related to the Site Visit must adhere to the principles of this Code of Conduct (i.e., modest in value, suortindate to the Site Visit, etc.) and all applicable laws.

17 Third Party Intermediaries

In many instances Medtech Canada member Companies engage Third Party Intermediaries (TPI) for the commercialization, distribution or sale of Medical Technology to HCP, HCI or GO. Such TPIs may fall under the description of distributors, agents, subagents, wholesalers, brokers, or independent sales agents.

Companies are generally held liable for actions and activities of their TPIs. Therefore, special attention should be given to ensure that TPIs undergo a full due diligence review prior to retaining such third parties. The Company's due diligence review of its TPIs should be updated on a regular basis (recommendation for at least every 3 years). More frequent updates are necessary whenever major changes occur with the TPI such as ownership changes, mergers, acquisitions, changes in executive leadership.

Medtech Canada emphasizes that it is the responsibility of each Company to ensure that its TPIs are made aware of and held accountable to comply with all applicable laws, industry standards and, to the extent applicable, the terms of this Code of Conduct. Medtech Canada provides further guidance through the "Joint Guidance for Medical Device Diagnostics Companies on Ethical Third-Party Sales and Marketing Intermediary (SMI)". In addition, training tools and other Due Diligence Resources are accessible through the Medtech Canada website.



Note: This 2022 Medtech Canada (formerly MEDEC) Code of Conduct supersedes and replaces all previous Medtech Canada Codes of Conduct. Companies will communicate the principles of this Code to their employees, and TPIs with the expectation that they will adhere to this Code. All Companies have an independent obligation to ascertain that their interactions with HCP, HCI or GO comply with all applicable laws and regulations. This Code of Conduct is intended to facilitate ethical behaviour, and is not intended to be, nor should it be, construed as legal advice. The Code is not intended to define or create legal rights, standards or obligations.



Medtech Canada Code of Conduct Glossary

Bona Fide Genuine, real; sincere, without intention to deceive and without unlawful or improper intent.

Charitable Donation The making of a financial or Medical Technology gift to a registered charitable organization with no expectation of benefit in return.

Charitable Organization Organizations that are recognized as a registered charity, have received a registration number from the Canada Revenue Agency and are exempt from paying tax on their revenue and are operated exclusively for charitable purposes (i.e., the relief of poverty, the advancement of Education or other purposes that benefit the community in a way the courts have said are charitable) and devotes its resources to charitable activities.

Company / Companies Medtech Canada member company / companies

Consultant / Consulting A HCP who is engaged by a Company to provide consulting services (e.g., acting as key opinion leaders, participation on advisory boards, speaking or presenting at Company-Conducted Medical Technology Training and Educational Programs and other similar collaboration and consulting opportunities) pursuant to a documented consulting agreement

Continuing Medical Education (CME) A specific form of continuing education that helps those in the medical / healthcare field maintain competence and learn about new and developing areas of their field. These activities may take place as live events, written publications, online programs, audio, video, or other electronic media.

Education / Educational Communicating information directly concerning or associated with the use of Companies' Medical Technology, including for example, information about disease states and the benefits of Medical Technology to treat or diagnose said states and/or improve patient outcomes.

Educational Grant A financial or in-kind Medical Technology contribution made to an HCI to support an Educational activity.

Entertain / Entertainment Any activity provided for the purpose of amusement or enjoyment. Includes, but is not limited to, dancing or arrangements where live music is the main or a material part of the attraction, sight-seeing trips, theatre excursions, sporting events, golf outings, golf tournaments and other leisure arrangements.

Government Official (GO) Includes any official or employee of a government agency or other governmental unit, political party, party official or candidate, or public international organization. Also includes officers and employees of government-owned companies, or companies substantially controlled by such governments.

Health Care Institution (HCI) Any institution, corporation, government body, agency or committee and any other organization involved in the purchase or other acquisition, supply or distribution, assessment, funding or recommendation of Medical Technology and/or the administration of Medical Technology. HCI includes, but is not limited to, those individuals or entities (such as group purchasing organizations, shared service organization, or other HCI related entities) that purchase, lease, recommend, use, train, arrange for the purchase or lease of, or prescribe Companies' Medical Technology in Canada.

Healthcare Professionals (HCP) Individuals and entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technology in Canada. This includes both clinical and non-clinical people who make product-related decisions of the sort listed. This is a broad definition, intended to encompass anyone with material influence over purchasing decisions. Note that there may be laws and other codes applicable to relationships with Healthcare Professionals, including relationships with government employees.

Medtech Canada Medical Technology Association of Canada

Medical Technology Medical devices, products, consumables, technologies, solutions and services used to help diagnose, treat, monitor, manage and alleviate health conditions and disabilities

Reasonable Appropriate, fair, sensible and moderate. Related to meals, travel, and accommodations, means in accordance with the Company's corporate travel and expense policies and the policies of the HCP, HCI or GO organization and their respective professional industry rules and laws, as applicable.

Satellite Symposia scientific/clinical programs that offer Educational content through faculty presentations, lectures, posters, etc. including CME and non-CME accredited activities

Site Visit An event in which an HCP or GO travels to a Company's location to participate in activities that cannot be provided at the HCP or GO's location, such as: demonstration of Medical Technology and observing the manufacturing process.

Sponsor / Sponsorship To provide funding to a particular organization or body.

Training Training on the safe and effective use of Medical Technology.

Third Party Educational Conference A conference or meeting conducted by or on behalf of national, regional, or specialty medical professional associations, accredited CME providers, or training organizations with a genuine educational purpose or function that is: a) independent and b) of an educational, scientific, or policy-making nature and for the genuine purpose of promoting scientific knowledge, medical advancement, or the delivery of effective healthcare.

Third Party Intermediary (TPI) Any third party that sells, or resells, or assists in selling or reselling any products manufactured or distributed by a Company, and receives a fee, commission, discount or other compensation for such services. Terms typically used to describe such third parties include broker, agent, enhanced agent, dealer, reseller, distributor, consultant, intermediaries, business partner or any representative acting on behalf of the Company in a sales capacity

Value Add A product, service or funding that is solicited by an HCI as part of their procurement process and offered by the Company to the HCI at no additional charge or on concessionary terms. Examples of Value-Adds may include rebates, discounts, Training or Research Grants. The Value-Add provides the HCI value or benefits above the specific Medical Technology being procured.