MEDEC

CANADA'S MEDICAL TECHNOLOGY COMPANIES
LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIES MÉDICALES

Transparency on Interactions Between the Medical Technology Industry and Health Care Providers

MEDEC POSITION

MEDEC is committed to ensuring fairness, transparency and supporting ethical behaviour in interactions between the medical technology industry and health care providers. As such, MEDEC is committed to working collaboratively with provincial and federal governments to ensure confidence in the integrity of the healthcare system and in supporting an open, collaborative and innovative medical technology sector in the best interest of patients.

MEDEC advises the provincial and federal governments to focus transparency efforts by leveraging evidence and best practices to inform any potential actions. Prior to making any changes or enhancements to transparency initiatives, it is important to understand what the current conflict of interest issues are, and how existing risk mitigation actions are either working to minimize or not. It is also important to ensure existing conflict of interest guidelines are being properly adhered to, and that there is appropriate awareness of them across the healthcare sector to support compliance.

Should there be concerns after appropriate review, MEDEC would advise the provincial and federal governments to consider focusing additional action using the following Guiding Principles:

1) Ensure measures to support transparency are based on evidence and in alignment with provincial imperatives: In looking at actions to support transparency, be clear on what problem is to be solved and align the actions with the outcomes desired. It will be important to avoid unintended impacts on innovation and economic growth, privacy legislation, procurement requirements and patient care.

2) Confirm what is appropriate in terms of scope: ensure the actions capture the specific areas of interest where there is concern to avoid casting a wide net with unintended impacts. As such, consideration should also be given to ensure proposed actions align with provincial and federal procurement policies and procurement/ tender requests to support healthcare system needs around areas such as education, training and research. In addition, it is important to leverage existing transparency initiatives and enhance others where evidence indicates to ensure the right activities are captured, in an efficient manner for both industry, health care providers and government.

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3) Build Upon Collaboration: Involve industry and other stakeholders actively to get the best insight on the current landscape, interdependencies and potential consequences of proposed actions. It is important to build on existing Code of Conduct initiatives, share best practices, lessons learned both here and globally in enhancing transparency to ensure confidence in the approach government takes.

4) Foster Positive Impact on Patient Care: Don't create barriers to innovation for patients, or try to solve one problem and create another. A critical part of any enhancements to transparency will be ensuring appropriate communication to ensure industry, health care providers and even patients understand why change is happening, why it is important and what will be the path forward.

5) Review and Update: Ensure any policies or actions are reviewed regularly to confirm the outcomes are appropriate, and revise as needed to improve them. In particular, reviews should ensure that limits are reasonable, reporting and monitoring requirements are simple, easily enabled and minimize costs for both government and vendors, clinicians are able to access the education and training they need to use medical technology appropriately, innovation opportunities are not lost (research, clinical trials, product development, early access to emerging technology), patients are able to access medical technologies in an efficient and effective way, and privacy and professional practice are respected.

BACKGROUND

Like many jurisdictions around the world, Canada's federal and provincial governments are increasingly focused on providing enhanced transparency and accountability into its activities as part of a broader commitment to open government. In doing so, they are also interested in ensuring a similar level of transparency with those they interact with. In the healthcare system in particular, there is a focus on greater collaboration across health service providers, researchers and industry, creating an interest in understanding and supporting what is appropriate in terms of transparency initiatives to ensure the public remains confident in the integrity of the system.

MEDEC understands the importance of maintaining public trust in the organizations and people delivering vital healthcare services, and is a committed partner with the public sector in supporting openness and transparency for its members, healthcare providers and for government. As an association representing medical technology companies across Canada, MEDEC believes strongly in creating an environment that supports collaboration and innovation to foster high quality patient care. This can only be done when there is trust, transparency and a mutual commitment to fairness in how activities are conducted, with a focus always on supporting practices that reinforce patient safety and the best quality of care for all Canadians.

The medical technology industry shares and has demonstrated government values around integrity, ethical conduct, and commitment to excellent patient care. MEDEC has had a long history of involvement with government in supporting initiatives for ethical conduct, including establishing an industry Code of Conduct more than 10 years ago, and collaborating to develop best practices for tendering, site visits and many other interactions. Such collaborations reflect the value of industry engagement to support transparency, recognizing the importance of facilitating appropriate interactions between medical technology companies and health services providers to advance patient care.

The MEDEC Code of Conduct is just one example of checks and balances that support ethical behavior across the medical technology sector and minimize the chance of conflict of interest. There are several others, including:

- **Legislation:** governing both local companies and multi-nationals that define and set penalties for conflict of interest. Examples include the *Criminal Code of Canada*[1] with provisions regarding behaviour of public servants and business conflict of interest, and internationally, the *Foreign Corrupt Practices Act*[2] in the United States concerning bribery of public officials.

- **Policy Directives:** across government, agencies, regulatory colleges and public organizations including:

    o **Procurement Directives:** of provincial and federal governments that set parameters and codes of conduct for the procurement process, including directives on how procurement is to be open, fair, transparent and non-discriminatory, such as the Ontario's *Broader Public Sector Procurement Directives*[3] and BC's *Core Policy and Procedures for Procurement*[4];

    o **Physician Association Policies:** that prescribe appropriate conduct for professional interactions between clinicians and industry, such as of the College of Physicians and Surgeons of Ontario's *Physician Relationship with Industry: Practice, Education and Research Policy*[5] or the College of Physicians and Surgeons of Alberta's *Standards of Practice*[6];

    o **Research Ethics Policies;** of Academic Health Centres and government research centres across Canada that govern the set-up, administration and reporting requirements of research studies. This includes Research Ethics Boards (REB) and associated policies and procedures, such as the REB pertaining to studies involving Health Canada[7];

    o **Codes of Conduct/Ethics Policies:** for Regulated Health Professionals across all provinces that guide standards of practice for clinician interactions with industry.

- **Industry Codes of Conduct:** for medical technology sector (MEDEC Code of Conduct[8], reviewed annually to reflect business and regulatory environment) and for the brand name pharmaceutical sector (Innovative Medicines Canada Code of Ethical Practices[9]).

TRENDS AND OBSERVATIONS ON TRANSPARENCY GLOBALLY

MEDEC members have experience elsewhere on how governments are supporting transparency around industry and healthcare provider interactions. Observations from other jurisdictions are helpful in understanding how Canadian governments at all levels can ensure they are appropriately addressing ethical behavior here at home. In particular, the following trends have emerged.

Area	Experience	Example
Thresholds	Minimum value to report has been very low relative to interaction	$10 threshold in the US, and €10 in France, capturing significant reporting of low value interactions, requiring same level of due diligence/effort as larger transactions.
Scope	Range of activity, individuals captured has often been far wider than anticipated/relevant	In Europe, captures both individuals and entities, including students and even ambulance drivers.[10]
Burden	Compiling, tracking, reporting costly for both industry, government	In the US, more than 11 million records generated in 2014[11] estimated to cost government $161M annually in reporting requirements. For individual companies, costs estimated at $500,000 annually.[12]
Patient Care	Scope/thresholds have inadvertently limited ability to provide training/education on technology, and potential access to innovations	In many regions, medical textbooks and journal articles are required to be reported, and MEDEC members have experienced some health care providers that are now not accepting educational offerings to reduce the burden of reporting.
Privacy	Extent of data capturing and reporting can be in contradiction to privacy legislation	Newer transparency laws in Europe (Sunshine Act in France, EFPIA for pharmaceuticals), have come up against data protection and privacy laws, resulting in court challenges and difficult implementations .[13]
Timelines	Some jurisdictions have done retroactively, others with limited communication on the "why" creating confusion, concern with health care providers and even patients	Belgium undertook a staggered approach, to drive education and awareness, with clearly defined scope and actively monitored privacy and consent.[14]
Innovation	Wide scope/thresholds limiting R&D activities	Since the introduction of the Sunshine Act in the US, initial data is showing a significant decline in industry support for research payments.[15]

ABOUT MEDEC

MEDEC is the national association representing the medical technology industry in Canada. Our members are committed to providing safe and innovative medical technologies that enhance patient care and advance patient outcomes. The medical technology industry in Canada employs over 35,000 Canadians in close to 1,500 corporate facilities, and has sales of nearly $7 billion per annum. We are committed to ensuring that Canada has a strong and vibrant medical technology industry.

References

1) Criminal Code of Canada http://laws-lois.justice.gc.ca/eng/acts/C-46/

2) United States Foreign Corrupt Practices Act http://www.justice.gov/sites/default/files/criminal-fraud/legacy/2012/11/14/fcpa-english.pdf

3) Government of Ontario Broader Public Sector Procurement Directives https://www.doingbusiness.mgs.gov.on.ca/mbs/psb/psb.nsf/Attachments/BPSProcDir-pdf-eng/$-FILE/bps_procurement_directive-eng.pdf

4) Government of British Columbia Procurement Guidelines http://www.fin.gov.bc.ca/ocg/fmb/manuals/CPM/06_Procurement.htm

5) College of Physicians and Surgeons of Ontario Physician Relationships with Industry Policy http://www.cpso.on.ca/Policies-Publications/Policy/Physicians-Relationships-with-Industry

6) College of Physicians and Surgeons of Alberta Standards of Practice http://www.cpsa.ab.ca/Libraries/Res_Standards_of_Practice/CPSA_Standards_of_Practice_Consolidated_Version.pdf

7) Health Canada Research Ethics Board http://www.hc-sc.gc.ca/sr-sr/pubs/advice-avis/reb-cer/index-eng.php

8) MEDEC Code of Conduct http://www.medec.org/page/Code_of_Conduct

9) Innovative Medicines Canada Code of Ethical Practices http://innovativemedicines.ca/ethics/code-of-ethics/

10) La base de données publique Transparence - Santé website https://www.transparence.sante.gouv.fr

11) Centres for Medicare and Medicaid Services Open Payments Data website https://openpaymentsdata.cms.gov/

12) Department of Health and Human Services. (2013). Final Rule, Affordable Care Act Section 6002.

13) French Supreme Administrative Court decision significantly broadens scope of the French 'Sunshine Act' (- Publications) http://www.reedsmith.com/French-Supreme-Administrative-Court-decision-significantly-broadens-scope-of-the-French-Sunshine-Act-03-18-2015/

14) Belgium Transparency Platform https://www.betransparent.be/en/

15) Open Payments Driving Adjustments in HCP Engagement Practices https://www.lifescicompliance.com/wp-content/uploads/2015/02/Life-Science-Compliance-Update.-August-2015.pdf