Improving Health Care, Transparency and the Business Climate in Ontario

Procurement Challenges in the Ontario Health Care System and Possible Solutions

A MEDEC submission to the Expert Panel on Supply Chain Review in Health Care
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Improving Health Care, Transparency and the Business Climate in Ontario

Procurement Challenges in the Ontario Health Care System and Possible Solutions

Introduction

MEDEC is the national association representing the Canadian medical technology industry. Our members create technologies that save patients’ lives, improve the quality of patient outcomes, reduce costs to the health care system, and create thousands of high paying jobs. The timely adoption of medical innovation and technology is essential to enhancing patient care, improving patient access to healthcare and enabling healthcare sustainability, while at the same time driving jobs and economic growth in Ontario.

The medical technology industry understands that the role of procurement professionals in Shared Services Organizations (SSOs) and Group Purchasing Organizations (GPOs) is to implement institutional acquisition decisions. These groups have the dominant role in executing these decisions; however they are not utilizing evaluation models which consider the entire value proposition of beneficial medical technology. As a result, Ontario is currently missing out on opportunities to achieve significant healthcare cost savings, improve patient outcomes and grow the province’s economy.

Strategic procurement objectives and processes need to be revised and updated to consider the value of technology across the entire health care system. In the current situation in Ontario, purchasing objectives are seldom aligned with the long-term objectives of the healthcare system or health benefits for patients. This is a time of great opportunity for working together to strategically align the buying objectives with the priorities and mandates of the healthcare system.

In addition, the actual administrative process, usually consisting of RFP’s (Request for Proposals), has become burdensome and expensive in health care. There are many opportunities to streamline processes and reduce the cumbersome nature of the current procurement environment. This would be of great benefit to the government, patients and to the health care system – while simplifying our system for suppliers and procurement organizations.

Through extensive consultations with the medical technology industry, MEDEC has prepared this report to highlight many of the barriers to success in the current environment, to provide specific examples of challenging situations and to offer some suggested solutions for the benefit of patients, sustainability of the health care system and to support a strong business climate on Ontario.
Section 1: Putting Patients First and Ensuring Health Care System Sustainability

In today’s medical technology environment, there are two distinct types of products and/or services that require procurement. In both cases, it is important to evaluate Price vs. Cost vs. Value and enable health care providers to choose technologies based on the best products for patient outcomes and the best value for the healthcare system. There are differences needed in the approach for each type of procurement.

The first area addresses products which are being treated as commodities, are fairly equal in technical aspects and application, and are established in the market. The second area involves enhanced, new or “disruptive” technologies, and applications which may be highly unique from each other. If the government and the procurers acknowledge the distinct areas of procurement and use alternative assessment techniques which differentiate between price and cost and value, the result will be significant improvements in patient care and better value for our healthcare dollars.

Today in Ontario, RFPs are the most common form of procurement and are usually being administered by a third party e.g. GPO or SSO on behalf of a hospital or group. Several issues are associated with this process which hinder the management and adoption of many innovative medical technologies that can provide benefits to patients and better value to the health care system.
Commodities vs. Enhanced Technologies

- RFPs typically apply an evaluation matrix which scores products and proposals as if they are evaluating a commodity and allows for very little variation in actual use, potential time/labour savings, pain impact, etc.
- While some classes of products are very similar and can be assessed and scored by a matrix, there are many clinical areas where improvements in work flow, staffing levels required, patient management and length of stay can be significantly affected by unique product features and improvements.

The Government should consider a differentiated procurement process for “commodities” vs. “innovations”

Innovations should include any medical technology or device where the difference between products can impact either 1) patient outcomes or 2) health care system savings/costs

Price vs. Cost vs. Value

- It would be ideal if hospitals could accurately assess proven or potential differences in products to establish value other than merely the quoted “price to buy”.
- Actual pricing may not reflect the impact on the entire case cost to the hospitals.
- A more expensive device may be a higher acquisition price for the OR but may save on drug expense, staffing, time required in ICU, or other health care costs.
- Some products will reduce hospital length of stay, patient recovery time and the ability to return to work.
- Data from case costing models would help with this type of thorough assessment but there is currently a lack of consistency in case costing within each hospital and little to no similarity across hospital groups, LHINs, regions or even the province.
- The current inability to assess holistically how technology may affect the patient pathway or alter the total case cost is potentially preventing advancements in care and savings to the system.

The Government should consider a model which maximizes the value they receive from the use of public funds. A “Value for Money” approach evaluates the total system cost to deliver goods and services and looks beyond simply procurement.
Rebates and Value-Adds to the Procurement Group

- Almost all GPOs and SSOs include requests for volume based rebates in their RFP documents.
- It is usually made very clear to suppliers that the potential dollar value of any rebates will be factored into the scoring of the proposal.
- Fees being paid to third party procurement organizations add significant expense to the purchasing process and provide funds to the purchasing organization but bring very little proven enhancement to patient care.
- In some cases, rebates are being paid to the procurers and are in addition to support or funding being paid to the Hospital.

Value-Adds, which are being requested as part of an RFP, should only be included if the value add is directly related to the products, service or related solutions being purchased.

Rebates and Value Adds should be voluntary, not mandatory.

MEDEC has developed a robust position paper on this topic.

See Appendix 1: “MEDEC Position Paper – Value-Adds in Competitive Tendering”
Section 2: Strengthening Accountability and Increasing Transparency

Over the last number of years, there has been an increased focus from federal and provincial governments to strengthen accountability and increase transparency in all government, including within Health Care and Procurement. Government mandates are designed to increase oversight, drive compliance and ensure fair business practices.

Coincidentally, in the medical technology industry, the same principles have been embraced and the industry has been self-regulating by creating codes of conduct to guide processes and relationships with customers and to ensure that MEDEC members operate consistently and with transparency.\(^1\)

Transparency and accountability for procurement organizations will ultimately deliver better value for Ontario patients and taxpayers. Many improvements in this area can be made including:

**Accountability for Finances/Taxpayer Dollars**

- GPOs/SSOs are funded through volume rebates and value-adds collected from suppliers based on contractual agreements.
- Hospitals actually purchase and utilize the contracted technologies, the GPO’s/SSO’s then receive rebates and value-adds back from suppliers; the money collected is used to finance the group purchasing organization.
- There is no transparency or direct oversight over the GPO/SSO finances
- At one time SSO employee salaries were listed, as applicable, on the Ontario Public Sector Salary Disclosure List; that practice is now inconsistent with few reporting and appearing on the list.
- Unlike hospitals, long term care or CCAC’s, there is not currently a provincial auditing opportunity over SSO’s/GPO’s.

The Ontario Government should adopt the following related recommendations in the “Standing Committee on Social Policy – Report on Diluted Chemotherapy Drugs”:

In order to maintain transparency and accountability, the government of Ontario, through legislative or other means, take those steps necessary to ensure that:

- group purchasing organizations and shared services organizations are subject to all aspects of the Broader Public Sector Accountability Act, 2010;
- the salaries of employees and executives of group purchasing organizations and shared services organizations are reported under the Public Sector Salary Disclosure Act, 1996;
- group purchasing organizations and shared services organizations are subject to audits by the Office of the Auditor General of Ontario;

See Appendix 2: “Standing Committee on Social Policy – Report on Diluted Chemotherapy Drugs”

\(^1\) See Appendix 7 & 8: “MEDEC Code of Conduct” & “MEDEC Medical Imaging Site Visit Guidance”
Feedback and De-Briefing

- The BPS guidelines are very clear that a debriefing process, and opportunity for suppliers to understand the rationale for the selection of successful vendors and contract awards, is a requirement post-RFP.
- There have been situations where the GPO’s and Hospitals each divest and redirect the responsibility for this feedback i.e. the Hospital says it is the GPO’s responsibility and the GPO says it is the Hospital’s responsibility. The net result was no feedback at all which violates the BPS guidelines.
- The supplier has no way to understand why they may have lost, failed to gain, or are locked out of the business opportunity in some cases for many years.
- Without valuable feedback, companies face a significant barrier to correct any business strategies or innovate on product enhancements that may be vital to the healthcare system and patient care.

Dispute Resolution and Third Party Oversight

- Currently there is no third party oversight or dispute resolution process in procurement.
- This is problematic because if, for example, a company has an issue with the RFP process itself or cannot get adequate clarification, they are forced to challenge the very people who made the decision in the first place.
- Generally medical device suppliers feel that by questioning or expressing dissatisfaction to the GPO’s or SSO’s, they may risk current and future business opportunities.
- It is important for suppliers to have an impartial and safe place to manage disputes and offer constructive feedback.

The Ontario Government should create a consistent, mandatory, transparent process for feedback and de-briefings to suppliers that has, if required, 3rd party oversight.

The Ontario Government should consider implementing a 3rd party mechanism which allows stakeholders to challenge the actions taken by a procurement group and to ensure transparency and accountability into the decision making processes of procurement groups.

One reference model that could be examined would be the “Procurement Review Process” of the Canadian International Trade Tribunal (CITT).

MEDEC has a position paper and a proposal to consider as a means to adopt and implement this recommendation.

Section 3: A Better and More Innovative Business Climate in Ontario

In addition to the impetus to improve accountability and transparency and to work towards improved patient care in a sustainable health care model, there is a definite focus on improving, attracting and creating a more innovative business climate in Ontario. There are excellent opportunities to facilitate the reduction of burdensome paperwork and duplication of effort, the creation of standardization and consistency in processes and, in general, improve the collaboration between industry, government and the health care system.

In 2016, there are many tools and programs already available to the various groups involved in procurement. Many of these resources have been created as a result of strong collaboration between industry, government and healthcare. The tools, however, are voluntary and are not often used in day to day practices, contributing to even more inconsistency in the system. For example:

**Duplication in RFP’s of Medical Device Licensing Requirements & Standards**

- The majority of products being sold by the medical device industry in Canada today require Health Canada approval before any marketing or sales can begin.
- It is also mandatory that manufacturers comply with ISO standards (International Standards Organization) in Canada.
- Significant investment is made by industry and taxpayers in Canada to regulate and manage the clinical safety and utilization of medical technology in the Canadian market. We have one of the most thorough and conservative systems in the world for approval, licensing and ongoing amendments of medical devices. There are also very clear rules in place to prevent companies from promoting or quoting on products that are not Health Canada approved.
- Regardless of the strict regulatory limitations already in place and the information already reviewed by Health Canada, RFP’s and other procurement documents frequently request extensive information on clinical data that has been already provided to, and is on file, at Health Canada. For a supplier preparing a proposal, resubmitting this data is time consuming and is an expensive duplication of effort. For taxpayers, it represents waste as two different levels of government are reviewing the same information.

The Ontario Government should consider reviewing duplicative procurement practices and requests on RFP’s where other standards are already in place

- For example, there should be one check box for “Licensed by Health Canada” (Y/N) and one check box for “Adherence to ISO Standards” (Y/N) instead of separate requests within an RFP for duplicative information

See Appendix 4: “Duplication of Health Canada Requirement and ISO Standards in Medical Device Procurement Practices”
Consistency in Procurement Documents

- Each GPO, SSO or Healthcare group appears to spend considerable time and resources in creating specific RFP’s or other procurement documents. As a result, suppliers need to invest a significant amount of time and staffing resources to understand, comply with and respond to each different request which is not standardized and vary in format, terms and conditions, and requirements.
- For example: considerable time, effort and tax dollars were invested to create procurement templates which are not being consistently used or referenced such as the HSCN (Health Supply Chain Network) “Templates for Terms and Conditions” and “Innovation Procurement Templates”
- This is expensive for both procurers and suppliers and negates the value of the collaborative work already completed.

The Ontario Government should consider mandatory standardization processes for procurement groups where possible

The Ontario Government should regularly monitor the adherence to such standardized processes, where the process has been developed in consultation between supplier and provider representatives (such as HSCN, MEDEC, the OHA, etc.)

See Appendix 5: “HSCN Common Tendering and Contracting Templates”

See Appendix 6: “HSCN Innovation Procurement Toolkit”

Improved Collaboration and Trust

- Throughout any RFP submission process, suppliers evaluate the cost of a potential business opportunity, assess the comparable market situation for fair pricing and programs and, based on the proposed RFP Terms and Conditions, submit a proposal. This is a lengthy, expensive process for both suppliers and procurers.
- Increasingly, terms, conditions and business opportunities for suppliers are being unilaterally altered post-award, during the transition period or within a contract term.
- This is not conducive to a productive business climate in Ontario.

The Ontario Government should consider 3rd Party oversight and a dispute resolution mechanism for procurement

"Procurement in health care organizations has typically focused on generating short-term savings in meeting day-to-day needs. A more strategic, value-based approach considers not only price but also other measures of value such as reduced service utilization (e.g., fewer hospital readmissions), increased quality of life, and economic benefits. By taking into account these wider dimensions of value, the Council believes strategic procurement can contribute to healthier populations, a more efficient health system, and the growth of Ontario’s health technology sector.”

No one has said it better than the Ontario Health Innovation Council. The province of Ontario has an incredible opportunity to make a significant contribution towards health care transformation and economic development in our province.


We know that value-based procurement is a powerful tool to achieve those goals. In fact, where medical devices sit at a less than 4% spend of total health care costs, shifting the landscape to invest in the right innovative medical technologies that have the ability to displace some of the other 96% of health care spend in our province, is likely the single most powerful tool to achieve that objective.

To accomplish this goal, we must move away from our current “cheapest price” culture in procurement where short term cost-containment efforts have not rendered the health system savings required to sustain our system. In fact, significant public resources are spent by the government and the health care system to control spending on medical technologies when – in reality – medical devices have a tiny proportional impact on total health care system costs. This has proven to be a fruitless effort.

At MEDEC, our goal is to harness the experience of our member organizations and work with the government to achieve our objectives of common interest. We hope that our feedback is valued and welcome, and we thank the Expert Panel for taking the time to review our submission.

Working together we can improve procurement in health care to enhance the ability of the medical technology industry to further improve the lives of Ontarians through high-quality health outcomes for patients, further healthcare system savings, and more jobs for Ontarians.

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 Consolidated List of Recommendations

1. The Government should consider a differentiated procurement process for “commodities” vs. “innovations”.

2. The Government should consider a model which maximizes the value they receive from the use of public funds. A Value for Money approach evaluates the total system cost to deliver goods and services and looks beyond simply pricing procurement.

3. Value-Adds, which are being requested as part of an RFP, should be voluntary not mandatory and should only be included if the value add is directly related to the products, service or related solution being purchased.

4. Group purchasing organizations and shared services organizations should be subject to all aspects of the Broader Public Sector Accountability Act, 2010.

5. The salaries of employees and executives of group purchasing organizations and shared services organizations should be reported under the Public Sector Salary Disclosure Act, 1996.

6. Group purchasing organizations and shared services organizations should be subject to audits by the Office of the Auditor General of Ontario.

7. The Ontario Government should create a consistent, mandatory, transparent process for feedback and de-briefings to suppliers post award that has, if required, 3rd party oversight.

8. The Ontario Government should consider implementing a 3rd party mechanism which allows stakeholders to challenge actions taken by a procurement group and to ensure transparency and accountability into the decision making processes of procurement groups.

9. The Ontario Government should consider reviewing duplicative procurement practices and requests on RFP’s, where other standards are already in place (such as Health Canada licensing requirements and ISO Standards).

10. The Ontario Government should consider mandatory standardization processes for procurement groups where possible and should enforce the existing templates, policies and guidance already in existence.
Appendices

As Referenced in the Submission

Appendix 1  MEDEC Position Paper – Value-Adds in Competitive Tendering
Appendix 2  Standing Committee on Social Policy – Report on Diluted Chemotherapy Drugs
Appendix 3  MEDEC Position Paper – Third Party Review Process for Procurement
Appendix 4  Duplication - Health Canada and ISO Requirements
Appendix 5  HSCN Common Tendering and Contracting Templates*

*(due to the extensive size of the documents, please see http://www.hscn.org/ctc-templates.aspx to gain access to these documents)

Appendix 6  HSCN Innovation Procurement Toolkit*

*(due to the extensive size of the documents, please see http://www.hscn.org/innovation-procurement-toolkit-.aspx to gain access to these documents)

Appendix 7  MEDEC Code of Conduct

Appendix 8  MEDEC Medical Imaging Site Visit Guidance*

*(includes the following 3 documents: 1) MEDEC Medical Imaging_Staging an Effective Site Visit Guidance Document_March 2016 Update, 2) MEDEC Medical Imaging_Guidance for Effective Product Demonstrations including Checklist_Diagnostic Imaging March 2016 Update, 3) MEDEC Medical Imaging_Guidance for On-Site Product Demonstrations Including Checklist_PACS April 2016)

Additional Important Resources (Articles/Research Papers of Interest)

Appendix 9  Has the Pendulum Swung too far? The Impact of Group Purchasing Organizations (GPOs) and Shared Services Organizations (SSOs) on Small and Medium Enterprises (SMEs) in the Medical Device Industry – Rick Audus

Appendix 10  Health Systems Should Buy Better - Fiona Miller
Appendix 1

MEDEC Position Paper – Value-Adds in Competitive Tendering
Value-Adds in Competitive Tendering

IN GENERAL

Healthcare systems in Canada use tendering processes for the procurement of medical devices and diagnostics technologies. These tendering processes are becoming increasingly complex with growing requests for value-adds and are requiring a significant allocation of resources. The medical device industry is concerned about the direction of requests for these value-adds and the “uneven playing field” that may result due to them.

This paper outlines MEDEC’s position regarding the definition of appropriate value-adds in a fair and transparent sourcing process.

MEDEC POSITION

It is MEDEC’s position that medical technology companies and their customers (i.e., Canadian hospitals) should not be expected to buy business through value-add or in any other form of transactional relationship. There should be no unlawful inducement through unrelated or indirect grants or donations.

Non-RFX Value-add Requests

In the event a university, hospital or other institution would like to request a grant or donation, or other grant or donation not related to a specific product or service sourcing need, MEDEC recommends that these requests follow a transparent process completed outside of an RFX process, one that respects all stakeholders’ business protocol guidelines as well as MEDEC’s Code of Conduct.

RFX Value-Add Requests

All RFX proponents should be bound by the same guidelines.

Acceptable Sourcing Protocol:

• Any request for a value-add must relate to the product(s) or service(s) requested in the RFX.
• The value-add request should be clearly defined and documented within the RFX document.
• An example of a directly related value-add would be supplier support to optimize patient outcomes for the proposed product(s) and/or service(s), such as training and education.
• Value-adds should not be a mandatory requirement of the RFX.
• When a proposal contains a separate price envelope, the values-adds should be presented exclusively in this price envelope or form their own envelope so that it does not influence the quality evaluation of the product. Furthermore, objective and strict evaluation grids should be used to counter balance the influence of the value-adds in the final overall evaluation.

What is a Value-Add?

A value-add is a product, service, or funding of any nature that is solicited in an RFX or offered by a supplier company as part of an RFX response at no additional charge or on concessionary terms.
Acceptable Supplier Protocol:

- Value-adds offered by a supplier should be clearly documented as part of the RFX response.
- The value-add should be limited to product(s) or service(s) provided for a related purpose and be reasonably necessary or useful for proper installation, use, or servicing of the product. It should contribute to more effective patient care.
- Value-adds should adhere to the MEDEC Code of Conduct, Canada’s anti-bribery and anti-corruption laws, and each company’s own code of conduct and ethics. Value-Adds should not promote an anticompetitive environment in any manner.

Unacceptable Value-Adds:

- Unrestricted value-adds, and value-adds that include items such as: cash payments to individuals or institutions, unrelated capital equipment, direct benefits to specific individuals, and/or donations or grants which do not relate to the medical device industry or the products or services in the RFX are not appropriate.
- Value-adds linked to, or in any way connected with, the purchase of products not requested on the RFX are not appropriate.
- An RFX requesting specific value-adds unrelated to the products or services being sourced are not appropriate.
- Mandatory value-adds are not appropriate for fair business practice.

Glossary

For the purposes of this position paper a Value-Add is defined as follows:

A value-add is a product, service, or funding of any nature that is solicited in an RFX or offered by a supplier company as part of an RFX response at no additional charge or on concessionary terms. The value-add provides additional benefit(s) to the contracting body or its affiliations over and above the specific product or service requested in the RFX.

The term “RFX” (Request For <business opportunity>) is used to represent any type of formal procurement process, such as Request for Information (RFI), Request for Proposal (RFP), Request for Quote (RFQ), or Request for Tender (RFT) from a Canadian healthcare institution, system or governing body.
Appendix 2

Standing Committee on Social Policy –

Report on Diluted Chemotherapy Drugs
STANDING COMMITTEE ON
SOCIAL POLICY

DILUTED CHEMOTHERAPY DRUGS

2\textsuperscript{nd} Session, 40\textsuperscript{th} Parliament
63 Elizabeth II
The Honourable Dave Levac, MPP
Speaker of the Legislative Assembly

Sir,

Your Standing Committee on Social Policy has the honour to present its Report and commends it to the House.

Ernie Hardeman, MPP
Chair

Queen’s Park
April 2014
STANDING COMMITTEE ON SOCIAL POLICY

MEMBERSHIP LIST

2nd Session, 40th Parliament

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Chair

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Vice-Chair

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*MIKE COLLE

VIC DHILLON*

CHERI DINOVO

ROD JACKSON**

HELENA JACZEK

PAUL MILLER
(Hamilton East–Stoney Creek)*

______________________________________________

Valerie Quioc Lim
Clerk of the Committee

William Short
Clerk of the Committee

Elaine Campbell
Research Officer

*Lorenzo Berardinetti, Margarett R. Best, Amrit Mangat, and Michael Mantha were replaced by Bas Balkissoon, Mike Colle, Vic Dhillon, and Paul Miller (Hamilton East–Stoney Creek) on September 9, 2013.

**Jane McKenna was replaced by Rod Jackson on October 11, 2013.

Christine Elliott, Cindy Forster, and France Gélinas regularly served as substitute members of the Committee.
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<td>CCO</td>
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INTRODUCTION

The Standing Committee on Social Policy is pleased to present its report on diluted chemotherapy drugs. The report is the culmination of many weeks of hearings, beginning in April 2013 in the aftermath of the discovery that 1,202 patients in Ontario and New Brunswick had received diluted doses of two admixed chemotherapy drugs: gemcitabine and cyclophosphamide. The hearings followed the Committee’s passage of a motion (see Appendix A) on April 15, 2013.

Key participants in the discovery and in the subsequent response appeared before the Committee in April, May, June, September, and October 2013, some of them more than once. A list of witnesses is found in Appendix B.

BACKGROUND

Medbuy, a national group purchasing organization (GPO), issued a request for proposals (RFP) for pharmaceutical products in 2008. Sterile preparation admixing services were included for the first time. Medbuy members, among them many Ontario hospitals, had encouraged the company to include these services as hospitals were already outsourcing them. The one submission received in response to the admixing portion of the RFP was from Baxter CIVA, which was awarded the contract. Two of the drugs involved were gemcitabine and cyclophosphamide; both were manufactured by Baxter.

With the Baxter contract due to expire in the fall of 2011, Medbuy made a public posting in March of that year announcing that the contract would be renewed. (Baxter was thought to be the sole provider of admixing services). Marchese Health Care (MHC) objected, saying that it could also provide such services. Medbuy staff visited a MHC facility, and then reported to Medbuy’s pharmacy

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1 Both drugs were received off-site in powder form, then mixed with saline and delivered to hospitals in IV bags. Witnesses used “admixing” and “compounding” to refer to the process used to prepare the drugs for hospital use; the Committee has chosen to use the former. Health Canada’s definition of compounding includes the following: “The combining or mixing together of two or more ingredients (of which at least one is a drug or pharmacologically active component) to create a final product in an appropriate form for dosing.” See Health Canada, Health Products and Food Branch Inspectorate, Policy on Manufacturing and Compounding Drug Products in Canada POL-0051 (issued January 26, 2009), p. 7.
2 The Ontario Hospital Association sent a survey regarding the use of pre-compounded (as opposed to pre-mixed) intravenous (IV) medication purchased from external providers to all Ontario hospitals in April 2013. Its analysis examined the responses of 88 of 129 acute care facilities, representing 94% of acute care beds. Fifty hospitals purchased the medication from external providers. Key reasons for purchasing from external providers included patient safety, Accreditation Canada standards, and occupational health and safety. See Ontario Hospital Association, Hospital Usage of Pre-Compounded Medications from an External Provider – OHA Survey Results: April 2013, pp. 1, 3 and 4.
3 Legislative Assembly, Standing Committee on Social Policy, Hansard, 2nd Sess., 40th Parl. (May 6, 2013), p. SP-104 (subsequent references to Hansard are, unless otherwise noted, to hearings of this Committee).
committee. All were satisfied that MHC could provide admixing services. (The pharmacy committee has about 25 members, many of them directors of pharmacy at their respective hospitals. It is led by Medbuy employees and discussed in greater detail on page 6.)

Because of MHC’s challenge, Medbuy was obligated to issue an RFP. During the RFP process, Baxter was asked to provide a list of items that Medbuy member hospitals were purchasing from the company. This list went to tender and included gemcitabine and cyclophosphamide as non-concentration specific admixtures.

The deadline for submissions was November 9, 2011. Submissions were received from Baxter, Gentès & Bolduc, and MHC. The RFP included a mandatory requirement that admixing services be supervised by a licensed pharmacist. MHC met this requirement and “warranted” that all of the pharmacists performing admixing services were licensed in Ontario, that it was a pharmacy licensed by the Ontario College of Pharmacists, and that it had consulted with Health Canada about additional requirements for meeting its regulations.

The three submissions were scored against a predetermined set of criteria established by members of Medbuy’s pharmacy committee. The criteria were based on four categories: pharmaceutical (maximum 30 points); label (maximum 30 points); financial (maximum 25 points); and business (maximum 15 points). All proponents were required to submit copies of their proposed labels (based on the list provided by Baxter), which were scored, the Standing Committee was told, against “precise label-scoring criteria.”

MHC received the highest score and was awarded the contract in the late fall of 2011. Before year-end, the Marchese organization created a new division, Marchese Hospital Solutions (MHS), to handle the Medbuy contract from a location in Mississauga. The contract was signed in February 2012; it included 117 products and was worth $2.6 million. The “overall spend” on gemcitabine and cyclophosphamide was about $10,000.

Under the terms of the contract, gemcitabine and cyclophosphamide were provided to the London Health Sciences Centre (LHSC), the Windsor Regional Hospital/Hôtel-Dieu Grace Hospital (WRH), Lakeridge Health, and a hospital in New Brunswick. The Peterborough Regional Health Centre (PRHC) was not part of the contract but received drugs through the Durham Regional Cancer Centre.

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4 Medbuy told the Committee the facility was in Hamilton. Marchese’s president said it was in Kitchener. See Hansard (May 6, 2013), p. SP-105; and Hansard (April 29, 2013), p. SP-88.
5 Hansard (May 6, 2013), p. SP-104.
7 Hansard (May 6, 2013), pp. SP-104 and SP-105.
8 Ibid.
part of Lakeridge Health. All facilities began using the MHS product at different points in time, with the PRHC being the last, as shown in the table below.

<table>
<thead>
<tr>
<th>LOCATION</th>
<th>FIRST USE OF MHS PRODUCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Windsor Regional Hospital</td>
<td>February 2012^{11}</td>
</tr>
<tr>
<td>New Brunswick</td>
<td>March 2012^{12}</td>
</tr>
<tr>
<td>London Health Sciences Centre</td>
<td>March and October 2012^{13}</td>
</tr>
<tr>
<td>Lakeridge Health</td>
<td>March 12, 2013^{14}</td>
</tr>
<tr>
<td>Peterborough Regional Health Centre</td>
<td>March 20, 2013^{15}</td>
</tr>
</tbody>
</table>

**Dilution Discovery**

On Tuesday, March 20, 2013, pharmacy assistants at the PRHC began to prepare gemcitabine for a patient’s afternoon chemotherapy treatment. The pharmacy’s supply of standard multi-patient use bags of admixed chemotherapy drugs from Baxter was depleted; product from MHS, the new supplier, was to be used for the first time.

The assistants noted differences between the two products. Unlike the Baxter bag, the MHS bag required refrigeration. Further examination of the MHS label showed that it did not include the total volume of the bag or the final concentration. A Baxter bag used for an earlier treatment that same day was still available. Its label read: four grams in 100 millilitres; total volume of 105.26 millilitres; gemcitabine 38 milligrams per millilitre. The MHS label indicated four grams in 100 millilitres. The assistants agreed that the final concentration on the MHS bag was unclear and uncertain.^{16} In order to comply with a physician’s order, they needed to know the specific concentration of the admixture.

The Baxter product had been prepared in an empty Viaflex infusion bag. MHS was using a pre-filled Hospira bag.^{17} (The Committee was told that there is a known industry standard that pre-filled IV bags are overfilled to account for


^{15} Hansard (May 7, 2013), p. SP-128.


^{17} Dr. Jake Thiessen, A Review of the Oncology Under-Dosing Incident: A Report to the Ontario Minister of Health and Long-Term Care (July 12, 2013), p. 16.
evaporation while in storage and that “overfill also addresses the issue of volume remaining in IV tubing.”

This lack of clarity resulted in PRHC staff contacting Lakeridge Health and Marchese. When asked if overfill had been taken into account, a Marchese representative said that it had not, leaving PRHC staff to conclude that MHS did not appreciate why concentration was important or how the product was being used.

(The Committee would learn that MHS was preparing the drugs in non-concentration-specific formats with the understanding that each bag would be used for a single patient. Even though the MHS labels were unlike those used by Baxter, the other hospitals were using the bags for multiple patients, as they had done when receiving product from Baxter. They did this under the misapprehension that the drugs had been prepared in concentration-specific formats, even though this was not the case and the label did not give the final concentration.)

In his report, *A Review of the Oncology Under-Dosing Incident*, Dr. Jake Thiessen wrote the following:

> MHS employed a process in the preparation of the bulk reconstituted cyclophosphamide and gemcitabine that failed to compensate adequately for an overfill factor in the supplier’s normal saline bags. On the basis of the MHS labels on the bags . . . , the best estimate is that the average actual cyclophosphamide concentration was 10% lower than that stated on the label. For gemcitabine the average actual concentration was 7% lower than stated on the label.

These findings in Peterborough led to the discovery that 1,202 patients at four hospitals in Ontario (PRHC, Lakeridge Health, WRH, and LHSC) and one in New Brunswick (a hospital in the Horizon Health Network) who had undergone chemotherapy treatment within the previous year, had received diluted doses of gemcitabine and/or cyclophosphamide. The table below shows the number of patients affected at each facility.

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<table>
<thead>
<tr>
<th>LOCATION</th>
<th>NUMBER OF PATIENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Windsor Regional Hospital</td>
<td>290</td>
</tr>
<tr>
<td>New Brunswick</td>
<td>183</td>
</tr>
<tr>
<td>London Health Sciences Centre</td>
<td>691</td>
</tr>
<tr>
<td>Lakeridge Health</td>
<td>37</td>
</tr>
<tr>
<td>Peterborough Regional Health Centre</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>1,202</strong></td>
</tr>
</tbody>
</table>

It was also learned that MHS, the company supplying the two drugs from its facility in Mississauga, was unregulated; neither the federal nor the provincial governments had oversight. To further complicate the issue, the contract for the provision of the two drugs was not between each of the hospitals and MHS, but between MHS’s parent company and Medbuy, the GPO contracted by the hospitals.

The Committee wishes to congratulate the pharmacy staff at the PRHC for their thoroughness, attention to detail, and initiative in bringing this matter forward to the relevant authorities. Most importantly, the Committee recognizes the fear and anxiety with which the affected patients and their families have lived since hearing their cancer treatments may have been compromised. It hopes that its comments and recommendations will help ensure that such an incident does not happen again.

**COMMITTEE OBSERVATIONS AND RECOMMENDATIONS**

Dr. Jake Thiessen’s report, *A Review of the Oncology Under-Dosing Incident*, was presented to the Minister of Health and Long-Term Care in July 2013 and released to the public the next month. He made 12 recommendations covering three areas: group purchasing organizations; manufacturing and compounding; and hospitals, clinics, and associated pharmacies. The recommendations appear in Appendix C.

The Committee generally endorses Dr. Thiessen’s recommendations. Because it sees its own efforts as complementary to those of Dr. Thiessen, the Committee has focussed its observations and recommendations on issues not specifically mentioned in his report or included in his recommendations. These issues relate to the procurement practices of hospitals; the oversight, monitoring and regulation of non-accredited pharmacies; and other concerns (i.e., labelling, communications, and best practices).

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21 Ibid., p. 11.
Procurement Practices of Hospitals

Medbuy is a private, share capital corporation and national GPO. It works under contract to health care organizations (e.g., individual hospitals, groups of hospitals and shared services organizations), which make up both its membership and its shareholders.

Medbuy has “about 25 full members and probably 75 hospitals.” Some members represent more than one facility. Medbuy’s board of directors is made up of 13 executives from shareholder members, who serve as volunteers, and two independent directors who receive financial compensation. Senior executives representing members also sit on the GPO’s advisory groups, like its pharmacy committee. Standing Committee members listened with skepticism as Medbuy representatives told them that it operates like a not-for-profit in that it does not retain earnings. Any net revenue generated is distributed to members in proportion to what they have spent under Medbuy contracts.

The pharmacy committee has about 25 members who are often directors of pharmacy in their respective hospitals/organizations. The committee is led by Medbuy employees who are also licensed pharmacists. It was this group that developed the scoring criteria for the 2011 RFP and evaluated submissions based on those criteria. The Standing Committee notes that it was also the pharmacy committee that failed to notice the contract’s lack of clarity with respect to the need for concentration-specific formats for gemcitabine and cyclophosphamide.

Health care organizations participate in GPOs for a variety of reasons. Those mentioned by witnesses included economies of scale, tighter purchasing practices, higher levels of standardization, and the ability to leverage training for new products and equipment.

While the Committee appreciates these reasons, it has the following concerns about the operation of GPOs: rebates, value adds, the application of provincial legislation, and audits.

22 Medbuy’s main competitor is HealthPRO.
23 A shared service organization (SSO) is “a centralized organization that BPS [broader public sector] institutions join as members to obtain better prices for goods and services through group purchasing.” See Office of the Auditor General of Ontario, Annual Report 2009, p. 202. Examples of SSOs in Ontario’s health sector include Plexxus, Shared Services West, and 3SO.
25 “Medbuy Briefing Note” attached to email from Medbuy Corporation, London to Clerk, Standing Committee on Social Policy, October 21, 2013.
26 Hansard (May 6, 2013), p. SP-104.
**Rebates**

Witnesses from Medbuy told the Committee that the revenue its activities generate is “rebate revenue.” Many contracts have a rebate structure based on meeting “certain volume thresholds.” If those thresholds are met, additional rebates are secured on behalf of members. The rebates go to Medbuy, which takes what it needs to offset its operating expenses and then distributes the remainder to its members.²⁶ (Medbuy’s annual budget is in the range of $7 million.²⁹) What a member receives is in proportion to what they spend under Medbuy contracts. The Committee was told that in 2012, member spend against Medbuy contracts was $627 million.³⁰

The Committee requested and received audited financial statements and rebate data from Medbuy, LHSC, WRH, and Lakeridge Health. Some of the latter appear in the table below. While not directly comparable, all are representative of the size of the transactions undertaken by Medbuy on behalf of its members.

<table>
<thead>
<tr>
<th>ORGANIZATION</th>
<th>2011/12</th>
<th>2012/13</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medbuy</strong>³¹</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rebates payable³²</td>
<td>$7,075,696.00</td>
<td>$6,339,395.00</td>
</tr>
<tr>
<td><strong>London Health Sciences Centre</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical rebates received from Medbuy³³</td>
<td>1,914,941.00</td>
<td>1,899,165.00</td>
</tr>
<tr>
<td><strong>Windsor Regional Hospital</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rebates received from Medbuy³⁴</td>
<td>462,389.37</td>
<td>409,292.21</td>
</tr>
<tr>
<td><strong>Lakeridge Health</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rebates received from Medbuy³⁵</td>
<td>1,006,199.75</td>
<td>530,048.48</td>
</tr>
</tbody>
</table>

²⁹ Ibid., p. SP-282.
³⁰ Ibid., p. SP-269.
³¹ Medbuy figures are for the calendar years 2011 and 2012.
³² Medbuy Corporation, *Financial Statements of Medbuy Corporation Year ended December 31, 2012*, “Balance Sheet.” These are rebates paid to all members, not just the three listed in the table. According to footnote 5 in the Statements, rebates payable included $1,163,239 (2011) and $1,104,366 (2012) in research, development and education (R.E.D.) funds. Information in email from Medbuy Corporation to Clerk, Standing Committee on Social Policy, October 21, 2013.
³³ London Health Sciences Centre, “Pharmaceutical Rebates Received from Medbuy Corporation Q1 2011/2012 through Q1 2013/2014.” Information in email from LHSC to Clerk, Standing Committee on Social Policy, October 21, 2013.
³⁴ Windsor Regional Hospital, “Summary of Rebates Received from Medbuy For the Fiscal Years Ending March 31, 2012 and 2013.” Information in email from WRH to Clerk, Standing Committee on Social Policy, October 15, 2013.
³⁵ Information in letter from Lakeridge Health, Oshawa to Clerk, Standing Committee on Social Policy, October 17, 2013.
Although appreciative of what was provided, the Committee remains concerned about the lack of transparency with respect to the receipt of rebates and how they are used, by hospitals and by Medbuy alike. Large amounts of public money are involved in these transactions, all of which are conducted without public oversight.

Value Adds

During the course of the hearings, the Committee learned about value-add incentives. The Ministry of Finance defined them as offers by suppliers over and above the primary goods or services being purchased, with the intent to increase the total value received by the customer.\(^{36}\)

These incentives are allowed under the Broader Public Sector Procurement Directive, but rules for their use include being “directly relevant and transparently connected” to a procurement.\(^{37}\) In the case of the Medbuy contract, Marchese’s offer included $20,000 for the GPO’s Research, Education and Development (R.E.D.) Fund. The Fund allocates money to healthcare industry initiatives, including training for the staff of Member hospitals.\(^{38}\) Marchese’s president told the Committee that the donation was a requirement of the contract but did not know how they came up with the $20,000 figure; she referred to it as a “neutral decision.”\(^{39}\) The Committee interpreted this as meaning a mutual decision made by Marchese and Medbuy.

Medbuy was asked if there was a value-add category included in the scoring process and provided the following response:

> There was at one point. There is no longer, and that’s probably been the practice for two or three years. We do not have a separate category of value add.\(^{40}\)

The Committee examined the 2011 Medbuy RFP for sterile compounding services and the submissions of Marchese’s competitors, Baxter and Gentès & Bolduc. The RFP included Schedule B, Value-Added Benefits, which were understood to mean the following:

> Any funds, goods or services provided to the benefit of Participating Medbuy Member(s) which are not identified as a mandatory submission requirement in this RFP document. [emphasis added] Value-Added


\(^{37}\) Ibid.

\(^{38}\) Medbuy, “R.E.D. Fund,” n.d.

\(^{39}\) *Hansard* (June 10, 2013), p. SP-239.

\(^{40}\) *Hansard* (September 23, 2013), p. SP-273.
Benefits are related to a particular Product(s) or Service(s) Contract without directly affecting the price(s) of product(s) listed in the submitted Proposal to this RFP. Medbuy encourages Proponents to submit Value-Added Benefits in the form of contributions to the Medbuy Research, Education, and Development (R.E.D.) Fund which will be scored as part of the Business Criteria.  

Contrary to what the Committee had heard, value-adds were included in Medbuy’s 2011 RFP. They were not a mandatory requirement but were encouraged and included in the score. Like Marchese, Baxter chose to participate in Schedule B; Gentès & Bolduc did not.

Application of Provincial Legislation

The Broader Public Sector Accountability Act, 2010 contains rules and accountability standards pertaining to the procurement of goods and services. Medbuy is considered a designated broader public sector organization under the Act because it is controlled by one or more designated broader public sector organizations (e.g., hospitals) and exists solely for the purpose of purchasing goods or services for them. The Broader Public Sector Procurement Directive, which applies to designated broader public sector organizations, has many mandatory requirements, one of which is an open competitive process for contracts with a procurement value of $100,000 or more.

The Committee acknowledges that Medbuy is compliant with the Broader Public Sector Accountability Act, 2010. It is also aware that Medbuy, as a GPO, is not obligated to adhere to all of the Act’s provisions.

Employee and Executive Salaries

Medbuy employs about 50 to 60 people; approximately 20% are licensed health care professionals. While some legislation does apply, Medbuy is not subject to the Public Sector Salary Disclosure Act, 1996. This statute requires organizations receiving funding from the province to disclose, on an annual basis, “the names, positions, salaries, and taxable benefits of employees paid $100,000 or more in a calendar year.”

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41 Attachment to letter from Gentès & Bolduc, St. Hyacinthe, Quebec, May 31, 2013 to Clerk, Standing Committee on Social Policy.
42 Ibid., and attachment to letter from Baxter Corporation, Mississauga, May 28, 2013 to Clerk, Standing Committee on Social Policy.
46 Ibid., p. SP-280.
47 Ministry of Finance, “Public Sector Salary Disclosure 2013 (Disclosure for 2012).”
Medbuy’s CEO was asked how many employees make over $100,000 and told the Committee “perhaps five.” In response to a request from the Committee, Medbuy provided staff compensation reports for 2011 and 2012. The report for 2012 contained 60 positions. Some of the titles attached to those positions were listed more than once (e.g., Analyst, Decision Support appeared three times). Individuals holding 17 of these positions made more than $100,000 that year. The Committee is disturbed by the discrepancy between this figure and that provided by the CEO.

**Audits**

The Committee learned that Medbuy can be audited but has not been the subject of what was referred to as “a full-blown audit.” Medbuy has provided supporting documentation about specific initiatives when asked to do so by the Broader Public Sector Supply Chain Secretariat of the Ministry of Government Services. The company’s annual financial statements are audited but audit results are not made publicly available.

In light of the dilution error and the amount of money being spent by hospitals and other health care organizations on drugs through nationally-based GPOs, the Committee believes that there is a need for greater openness and transparency in the way these bodies operate in the province of Ontario and makes the following recommendations.

<table>
<thead>
<tr>
<th>The Standing Committee on Social Policy recommends that</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The Ministry of Health and Long-Term Care examine best practices for the procurement and distribution of oncology drugs by provincial cancer centres. Areas to be examined would include, but not be limited to oversight.</td>
</tr>
<tr>
<td>2. In order to maintain transparency and accountability, the government of Ontario, through legislative or other means, take those steps necessary to ensure that</td>
</tr>
<tr>
<td>- group purchasing organizations and shared services organizations are subject to all aspects of the <em>Broader Public Sector Accountability Act, 2010</em>;</td>
</tr>
<tr>
<td>- the salaries of employees and executives of group purchasing organizations and shared services organizations are reported under the <em>Public Sector Salary Disclosure Act, 1996</em>;</td>
</tr>
<tr>
<td>- group purchasing organizations and shared services organizations are subject to audits by the Office of the Auditor General of Ontario;</td>
</tr>
</tbody>
</table>

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49 “2012 Compensation Report,” attached to email from Medbuy Corporation to Clerk, Standing Committee on Social Policy, October 21, 2013.
• public and broader public sector members of group purchasing organizations and shared services organizations pay for the value of procurement services as opposed to a percentage of purchases; and
• rebates and value adds are discontinued.

Oversight, Monitoring, and Regulation of Non-Accredited Pharmacies

Shortly after the public revelation that the gemcitabine and cyclophosphamide admixtures supplied by MHS were diluted, it was learned that the enterprise operated without provincial or federal oversight.

MHC was awarded the contract to supply intravenous admixtures to Medbuy member hospitals, and formed MHS, in late 2011. MHS was created as a separate division to keep the operations of Marchese’s hospital admixtures supply business separate from its community-based and home care pharmacies. The Committee was told that Marchese made contact with both Health Canada and the Ontario College of Pharmacists (OCP) in its unsuccessful attempts to find an oversight/regulatory body for MHS.53

In the words of a witness from the Ministry of Health and Long-Term Care,

Marchese, the company that mixed and supplied these drugs to the hospitals, fell into a gap between [Health Canada and the Ontario College of Pharmacists]. They were producing these drugs in a facility that was neither a pharmacy nor licensed as a manufacturer. It was a grey area, and consequently, there was no active oversight.54

Oversight at Time of Discovery

The OCP regulates and accredits community pharmacies under the Drug and Pharmacies Regulation Act. This Act also specifies that the OCP does not have jurisdiction over hospital pharmacies. Pharmacists and pharmacy technicians, in both community and hospital settings, are regulated by the OCP under the Pharmacy Act, 1991.

Health Canada regulates the manufacture, packaging, labelling, and sale of drugs, and licensed drug manufacturers, all under the Food and Drug Act. The Act also provides Health Canada with inspection powers in those places where drugs are manufactured, prepared, packaged or stored. Health Canada’s Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051)

53 The Committee was also told that Baxter, the incumbent provider, was not an accredited pharmacy. See Hansard (May 6, 2013), p. SP-109.
54 Hansard (April 22, 2013), p. SP-34.
includes a diagrammatic representation of provincial and federal jurisdiction over manufacturing and compounding, a re-creation of which appears below.

**Source:** Health Canada, Health Products and Food Branch Inspectorate, *Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051)* (July 30, 2009), p. 4.

**Provincial Response**

Cancer Care Ontario (CCO) issued a press release on April 2, 2013 announcing that patients at four Ontario hospitals who had undergone chemotherapy treatment within the past year had received lower than intended doses of cyclophosphamide and gemcitabine.\(^{55}\)

The following day, an OCP-appointed investigator and two Health Canada inspectors went to Marchese’s Mississauga site. They learned that MHS and an accredited MHC pharmacy occupied the same building. Both entities were visited. MHS had a pharmacist on-site, but the facility was not listed as a pharmacy with the OCP.\(^{56}\) On April 8 the OCP publicly acknowledged that MHS was not an accredited pharmacy and was outside of its regulatory authority and inspection


\(^{56}\) Ibid., pp. SP-15 and SP-18; and *Hansard* (May 6, 2013), p. SP-114.
process. Its investigation proceeded with a focus on the pharmacist, a member of the OCP.\textsuperscript{57}

In early April the Ministry of Health and Long-Term Care struck a working group of stakeholders to coordinate a response.\textsuperscript{58} It also selected Dr. Jake Thiessen, founding director of the University of Waterloo School of Pharmacy, to lead an independent review of “quality assurance in the province’s cancer drug supply chain.”\textsuperscript{59} His report was released in August.

Later in April the Ministry wrote to businesses it thought might be selling admixed drugs, in order to obtain information about their processes and oversight. Another letter was written to hospitals inquiring about admixing drugs.\textsuperscript{60} Over the following weeks, regulatory amendments were introduced requiring hospitals to purchase drugs from regulated suppliers, and expanding the jurisdiction of the OCP to oversee pharmacists and pharmacy technicians in drug preparation premises, including MHS.\textsuperscript{61}

The Committee notes that legislation responding to Dr. Thiessen’s recommendations was introduced on October 10, 2013. One of its provisions would allow the OCP to accredit and inspect pharmacies in public and private hospitals.

\textbf{Federal Response}

Health Canada issued an interim direction to companies involved in admixing in mid-April. The direction outlined the conditions under which these activities would be allowed: 1) in a manner that meets federal licensing and manufacturing requirements 2) within a hospital meeting provincial regulatory requirements; or 3) if outside a hospital, under the supervision of a provincially licensed pharmacist.\textsuperscript{62} The Committee notes that Marchese had been admixing under the supervision of a provincially licensed pharmacist.

\textsuperscript{57} \textit{Hansard} (May 6, 2013), p. SP-115.
\textsuperscript{58} \textit{Hansard} (April 22, 2013), p. SP-34.
\textsuperscript{60} \textit{Hansard} (April 22, 2013), pp. SP-34, SP-35 and SP-41.
\textsuperscript{61} Ibid., p. SP-35; and \textit{Hansard} (May 27, 2013), p. SP-185.
Following the directive’s release, companies performing admixing activities were asked which of the three categories the activity fell under. Health Canada has also worked with provincial and territorial government officials and pharmacist representatives.\(^{63}\)

The Committee heard that there is significant variation in the way provinces and territories oversee admixing. Members were told that the federal government will continue to exempt what was referred to as “traditional compounding” from its purview, but will focus on activities that appear to be a hybrid between “compounding and manufacturing.”\(^{64}\) It is considering the creation of a new category called commercial compounding-manufacturing, as part of its *Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051)*.\(^{65}\) The Committee notes that admixing by anyone other than a manufacturer continues to be unregulated.

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### The Standing Committee on Social Policy recommends that

3. Health Canada act on its intent to create a new category (i.e., commercial compounding-manufacturing) within its *Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051)*.

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### Other Concerns

#### Labelling

During its hearings, hospital representatives told the Committee that Marchese’s labelling was considered clearer and more precise than that of its competitors for the Medbuy contract.\(^{66}\) One of those competitors, Baxter, was told in a debriefing that one of the issues related to its bid was labelling.\(^{67}\) Members find this discomforting as it was the MHS labelling that first alerted the staff at PRHC to a possible problem with both gemcitabine and cyclophosphamide. The Baxter labels had been used without issue.

In August 2009 CCO issued recommendations related to key components of chemotherapy labelling which focussed on the necessary components and formatting of labels to maximize safe delivery and minimize errors. These guidelines were not designed for admixing facilities. They were intended for the preparation of chemotherapy drugs for individual patients in cancer centres rather than in facilities such as that operated by MHS.\(^{68}\)

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\(^{63}\) *Hansard* (October 21, 2013), p. SP-316.

\(^{64}\) Ibid., p. SP-317. A witness from Health Canada described “traditional compounding” as “making a specific dose for a specific patient to meet a specific need.” See ibid., p. SP-321.

\(^{65}\) *Hansard* (October 21, 2013), p. SP-319.


\(^{67}\) *Hansard* (June 4, 2013), p. SP-225.

\(^{68}\) *Hansard* (April 16, 2013), p. SP-10; and *Hansard* (April 29, 2013), pp. SP-77 and SP-78.
The Standing Committee on Social Policy recommends that

4. Cancer Care Ontario develop labelling guidelines for the preparation of chemotherapy drugs at provincial admixing facilities like that operated by Marchese Hospital Solutions.

5. The federal government, in consultation with the provinces, consider the introduction of:

- national standards for the labelling of concentration-specific and non-concentration-specific drugs; and
- national standards for the labelling of all admixed (i.e., narcotic, chemotherapy, and epidural) drugs (e.g., single patient use versus multiple patient use).

Communications

The Medbuy contract saw MHS start to supply members with gemcitabine and cyclophosphamide admixtures in February 2012. MHS’s understanding of the contract was that it was required to supply both drugs in non-concentration-specific formats and that each bag would be used for a single patient.  

As stated earlier in the report, the hospitals were using the bags for multiple patients with the understanding that the drugs were prepared in concentration-specific formats.

The Committee heard that a Marchese pharmacist and a Medbuy manager, who is a pharmacist, had an email exchange in January 2012 regarding the chemotherapy preparations and the attachment of lines or tubes to bags. Marchese asked about the possibility of attaching a line to the bags as a safety precaution. Medbuy replied that it did not expect Marchese to attach lines for the following reason:

the line set-up is likely different for each member. . . .

Members will be putting on a patient specific label in the Pharmacy and can attach a line if desired, at that time.

Marchese took this to mean that Medbuy understood the bags would be used for a single patient.

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70 Ibid.
71 Email 9 (17 Jan. 2012 – 2:54 pm) in package sent by Gowling LaFleur Henderson LLP, Toronto to Clerk, Standing Committee on Social Policy, October 9, 2013.
72 Hansard (June 10, 2013), p. SP-235.
Another email exchange involving the same Marchese and Medbuy staff members, also in January 2012, saw the former write the following:

a) Lakeridge has indicated their volumes for Gemcitabine 4g/105mL. We were planning on preparing this as 4g/100mL, as listed.\(^{73}\)

After checking its labels, Medbuy replied as follows:

the Baxter product was 4g in 105 mL. I don’t see any clinical impact from changing the volume but suggest that you decide what your preference is and then discuss with Lakeridge to see if they have any objections.\(^{74}\)

The Committee believes the above responses were inappropriate and are evidence of a lack of due diligence on the part of health care professionals. It sees these communications as more missed opportunities to catch the need for concentration-specific admixtures and avoid the circumstances of March 20, 2013 and their negative impact on 1,202 patients.

Pharmacists who work with oncology drugs on a regular basis told the Committee that the need to know the precise concentration of these medications was vital as a dose had to be individualized for each patient. An oncologist prescribes a dose that is based on a variety of factors (e.g., patient weight and type of cancer) that are unique to an individual. Concentrations are also adjusted according to a patient’s side effects.

The Committee also heard that, according to the product monograph for gemcitabine, in order for a four-gram dose to be used for one standard five-foot-ten patient, that individual would have to weigh over 900 pounds.\(^{75}\) This information is readily available to any pharmacist.

Four Marchese pharmacists involved in the start-up of the Medbuy contract admitted to having limited experience with oncology drugs. The MHS pharmacist who responded to PRHC’s inquiries on March 20 had no practical experience with chemotherapy drugs prior to working at MHS.\(^{76}\)

Best Practices

PRHC was one of four Ontario hospitals receiving gemcitabine and cyclophosphamide admixtures as part of Medbuy’s contract with MHS. As shown in the table on page 3, it was also the last to start using either product. Three of the other four facilities had been employing MHS products in their treatments for approximately a year.

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\(^{73}\) Email 5 (9 Jan 2012 – 5.24 pm) in package sent by Gowling LaFleur Henderson LLP

\(^{74}\) Email 7 (10 Jan. 2012 – 1:23 pm) in package sent by Gowling LaFleur Henderson LLP.

\(^{75}\) Hansard (June 4, 2013), p. SP-230.

\(^{76}\) Hansard (June 10, 2013), pp. SP-241 and SP-246.
Committee members are perplexed by the fact that pharmacists and pharmacy assistants/technicians at WRH, LHSC, and Lakeridge Health failed to notice the inconsistencies discovered by the staff at PRHC when preparing for the initial use of MHS gemcitabine.

The Committee is concerned about the professional conduct of pharmacists connected to this incident, including those employed by Medbuy and sitting on its pharmacy committee. This concern is so significant that the Committee has written to the Registrar of the Ontario College of Pharmacists (OCP) requesting an investigation. Copies of letters sent by the Committee to the OCP are found in Appendix D.

Accreditation Canada was contacted to determine what if any protocols it had dealing with GPOs and SSOs. In its response, the organization referred to medication management standards and leadership standards. Medical management standards address labelling and monitoring the quality of contracted services. The contents of Accreditation Canada’s response are found in Appendix E.

The Standing Committee on Social Policy recommends that

6. Ontario hospitals, and any group purchasing or shared services organizations which obtain medications on their behalf, ensure strict adherence to the relevant standards set by Accreditation Canada.

CONCLUSION

In April 2013 the Standing Committee on Social Policy began its work on the motion found in Appendix A. The scope of that exercise quickly expanded as the Committee learned more about the circumstances leading to the discovery that the gemcitabine and cyclophosphamide provided to five hospitals by Marchese Hospital Solutions were diluted.

Over time, the Committee heard about mistakes and missed opportunities to detect problems with the preparation of the two drugs before they were used by any of the hospitals involved. Members know that the outcomes for all involved would have been much different had the following occurred:

- the members of Medbuy’s pharmacy committee noticed the lack of clarity in the list of drugs put out to tender;
- staff at Medbuy and Marchese paid greater heed to the content and context of their email correspondence; and
- the staff at the Windsor, New Brunswick, London, and Lakeridge Health hospitals been as alert as those at the Peterborough Regional Health Centre to the differences between the labels on the Baxter and Marchese products.

The Committee has never lost sight of the effect that this incident has had on the lives of the 1,202 patients, adults and children, who received diluted
chemotherapy treatments, as well as their families. It hopes that its recommendations and the responses to them will help to ensure that similar situations are avoided in the future and that the public’s faith in the province’s health care system is maintained.

**CONSOLIDATED LIST OF RECOMMENDATIONS**

The Committee requests that those to whom recommendations are directed provide the Committee Clerk with a written response within 120 calendar days of the tabling of this report with the Speaker of the Legislative Assembly.

**The Standing Committee on Social Policy recommends that**

1. The Ministry of Health and Long-Term Care examine best practices for the procurement and distribution of oncology drugs by provincial cancer centres. Areas to be examined would include, but not be limited to oversight.

2. In order to maintain transparency and accountability, the government of Ontario, through legislative or other means, take those steps necessary to ensure that

   - group purchasing organizations and shared services organizations are subject to all aspects of the *Broader Public Sector Accountability Act, 2010*;
   - the salaries of employees and executives of group purchasing organizations and shared services organizations are reported under the *Public Sector Salary Disclosure Act, 1996*;
   - group purchasing organizations and shared services organizations are subject to audits by the Office of the Auditor General of Ontario;
   - public and broader public sector members of group purchasing organizations and shared services organizations pay for the value of procurement services as opposed to a percentage of purchases; and
   - rebates and value adds are discontinued.

3. Health Canada act on its intent to create a new category (i.e., commercial compounding-manufacturing) within its *Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051)*.

4. Cancer Care Ontario develop labelling guidelines for the preparation of chemotherapy drugs at provincial admixing facilities like that operated by Marchese Hospital Solutions.

5. The federal government, in consultation with the provinces, consider the introduction of:

   - national standards for the labelling of concentration-specific and non-concentration-specific drugs; and
national standards for the labelling of all admixed (i.e., narcotic, chemotherapy, and epidural) drugs (e.g., single patient versus multiple patients).

6. Ontario hospitals, and any group purchasing or shared services organizations which obtain medications on their behalf, ensure strict adherence to the relevant standards set by Accreditation Canada.
APPENDIX A

Committee Motion

That pursuant to Standing Order 111(a), the Standing Committee on Social Policy immediately initiate a study and investigation regarding recent reports where diluted chemotherapy drugs were administered to patients in Ontario; and, whether or not the Ministry of Health and Long-Term Care effectively exercised its role into the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

That the Committee shall be able to call witnesses under oath as it sees fit to assist in the Committee’s investigation and shall produce a report that includes, but is not limited to:

- investigating the apparent lack of oversight, lack of standards and/or absent monitoring for companies like, Marchese Hospital Solutions, by the Minister of Health and Long-Term Care;
- assessing the adequacy of Ministry of Health’s outsourcing strategy, pharmaceutical regulatory regime, guidelines and drug inspection procedures and protocols;
- any impact on the nearly 1,200 cancer patients in Ontario who received a flawed or diluted drug during their cancer treatments;
- whether the steps taken by the government and/or the Ministry and/or the Minister were adequate in responding to this matter;
- what international best practices could have and should have been used to ensure proper checks and balances were and are put in place for companies that produce complex drugs and the hospitals that use those drugs so as to prevent a situation like this from ever happening again;
- investigating the roles, respectively, of the Ministry of Health and Long-Term Care, the Ontario College of Pharmacists, Health Canada, and any other organizations the Committee might identify in overseeing, providing standards for, and monitoring companies like Marchese Hospital Solutions.

Notwithstanding the Committee’s meeting schedule as ordered by the House, the Committee shall seek permission from the House Leaders and of the House to be permitted to sit to the call of the Chair and to meet notwithstanding prorogation.

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77 Hansard (April 15, 2013), pp. SP-4 – SP-5.
## APPENDIX B

### List of Witnesses and Submissions

<table>
<thead>
<tr>
<th>ORGANIZATION/INDIVIDUAL</th>
<th>DATE(S) OF APPEARANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baxter Corporation Canada</strong></td>
<td></td>
</tr>
<tr>
<td>- Carol Bentley, Regional Director of Sales</td>
<td></td>
</tr>
<tr>
<td>- Phil Lynch, Director of Quality</td>
<td>June 4, 2013</td>
</tr>
<tr>
<td>- Anne Miao, Director of Pharmacy</td>
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<tr>
<td>- Mike Oliver, General Manager</td>
<td></td>
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<tr>
<td><strong>Cancer Care Ontario</strong></td>
<td></td>
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<tr>
<td>- Dr. Michael Sherar, President and CEO</td>
<td>April 16, 2013</td>
</tr>
<tr>
<td>- Dr. Carol Sawka, Vice President, Clinical Programs and Quality Initiatives</td>
<td>April 29, 2013</td>
</tr>
<tr>
<td><strong>Central East Local Health Integration Network</strong></td>
<td></td>
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<tr>
<td>- Wayne Gladstone, Chair, Board of Directors</td>
<td>May 13, 2013</td>
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<tr>
<td>- Deborah Hammons, CEO</td>
<td></td>
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<tr>
<td><strong>Erie St. Clair Local Health Integration Network</strong></td>
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<tr>
<td>- Gary Switzer, CEO</td>
<td>May 13, 2013</td>
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<tr>
<td><strong>Health Canada</strong></td>
<td></td>
</tr>
<tr>
<td>- Dr. Supriya Sharma, Senior Medical Adviser, Health Products and Food Branch</td>
<td>October 21, 2013</td>
</tr>
<tr>
<td><strong>Lakeridge Health</strong></td>
<td></td>
</tr>
<tr>
<td>- Kevin Empey, President and CEO</td>
<td>April 23, 2013</td>
</tr>
<tr>
<td>- Dr. Leta Forbes, Chief and Medical Director, Oncology Program; Quality Lead, Systemic Therapy, Central East LHIN</td>
<td>April 23, 2013</td>
</tr>
<tr>
<td>- Nancy Froude, Pharmacist, Durham Regional Cancer Centre</td>
<td>June 3, 2013</td>
</tr>
<tr>
<td>- Tom McHugh, Vice President, Clinical Services; Regional Vice President, Cancer Services, Central East LHIN</td>
<td>April 23, 2013</td>
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<tr>
<td>- Leslie Motz, Senior Director, Clinical Services</td>
<td>April 23, 2013</td>
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<tr>
<td>ORGANIZATION/INDIVIDUAL</td>
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<tr>
<td><strong>London Health Sciences Centre</strong></td>
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<tr>
<td>Murray Glendining, Acting CEO; Executive Vice President, Corporate Services and Clinical Support</td>
<td></td>
</tr>
<tr>
<td>Sandy Jansen, Director, Pharmacy Services</td>
<td></td>
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<tr>
<td>Neil Johnson, Vice President, Cancer, Renal and Pharmacy Services; Regional Vice President, Cancer Care Ontario</td>
<td>April 29, 2013</td>
</tr>
<tr>
<td>Tony LaRocca, Vice President, Community and Stakeholder Relations</td>
<td></td>
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<tr>
<td>Toby O’Hara, General Manager, Health Care Materials Management Services</td>
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<tr>
<td><strong>Marchese Health Care/Marchese Hospital Solutions</strong></td>
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<tr>
<td>Janie Bowles-Jordan, Pharmacist, MHC</td>
<td>June 10, 2013</td>
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<tr>
<td>Kathy Cuerrier, Pharmacist, MHC</td>
<td>June 10, 2013</td>
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<tr>
<td>Sophia Francis-Pringle, Pharmacist, MHC</td>
<td>June 10, 2013</td>
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<tr>
<td>Stephanie Gilbreath, Pharmacist, MHC</td>
<td>June 10, 2013</td>
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<tr>
<td>Kawther Salman, Pharmacist, MHS</td>
<td>June 10, 2013</td>
</tr>
<tr>
<td>Laura Savatteri, Pharmacist, MHC</td>
<td>June 3, 2013</td>
</tr>
<tr>
<td>Roberta Young, Infusion Technician, MHS</td>
<td>June 10, 2013</td>
</tr>
<tr>
<td>Marita Zaffiro, President</td>
<td>April 29, 2013; June 10, 2013</td>
</tr>
<tr>
<td><strong>Medbuy Corporation</strong></td>
<td></td>
</tr>
<tr>
<td>Michael Blanchard, Vice President, Pharmacy, Clinical Services and Business Development</td>
<td>May 6, 2013; September 23, 2013</td>
</tr>
<tr>
<td>Ann Kelterborn, Director, Strategic Sourcing and Member Services, Pharmacy</td>
<td>September 23, 2013</td>
</tr>
<tr>
<td>Kent Nicholson, President and CEO</td>
<td>May 6, 2013; September 23, 2013</td>
</tr>
<tr>
<td>Ron Swartz, Manager, Clinical Services and Patient Safety, Pharmacy</td>
<td>September 23, 2013</td>
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<tr>
<td><strong>Ontario College of Pharmacists</strong></td>
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<tr>
<td>Marshall Moleschi, Registrar</td>
<td>April 16, 2013; May 6, 2013</td>
</tr>
<tr>
<td>ORGANIZATION/INDIVIDUAL</td>
<td>DATE(S) OF APPEARANCE</td>
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<tr>
<td>Ontario Hospital Association</td>
<td></td>
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<tr>
<td>• Pat Campbell, President and CEO</td>
<td>May 13, 2013</td>
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<tr>
<td>• Sudha Kutty, Director, Patient Safety, Physician and</td>
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<tr>
<td>Professional Issues</td>
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<tr>
<td>Ontario Ministry of Health and Long-Term Care</td>
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<tr>
<td>• Catherine Brown, Assistant Deputy Minister, Health</td>
<td>April 22, 2013</td>
</tr>
<tr>
<td>System Accountability and Performance Division</td>
<td></td>
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<tr>
<td>• Saād Rafi, Deputy Minister</td>
<td>April 16, 2013</td>
</tr>
<tr>
<td>Peterborough Regional Health Centre</td>
<td></td>
</tr>
<tr>
<td>• Laura Freeman, Vice President, Clinical Services</td>
<td>April 30, 2013</td>
</tr>
<tr>
<td>• Sarah Hickey, Pharmacist, Cancer Clinic</td>
<td>May 27, 2013</td>
</tr>
<tr>
<td>• Dr. Peter McLaughlin, Chief Medical Officer; Vice</td>
<td>April 30, 2013</td>
</tr>
<tr>
<td>President, Clinical and Support Services; Chair, Medical</td>
<td></td>
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<tr>
<td>Advisory Committee</td>
<td></td>
</tr>
<tr>
<td>• Ken Tremblay, President and CEO</td>
<td>April 30, 2013</td>
</tr>
<tr>
<td>• Judy Turner, Senior Pharmacy Assistant, Cancer Clinic</td>
<td>May 7, 2013</td>
</tr>
<tr>
<td>• Lori Webb, Pharmacy Assistant, Cancer Clinic</td>
<td>Written submission</td>
</tr>
<tr>
<td>• Brenda Weir, Director, Emergency, Lab, Diagnostic Imaging and Pharmacy</td>
<td>April 30, 2013</td>
</tr>
<tr>
<td>• Craig Woudsma, Pharmacy Assistant, Cancer Clinic</td>
<td>May 7, 2013</td>
</tr>
<tr>
<td>South West Local Health Integration Network</td>
<td></td>
</tr>
<tr>
<td>• Michael Barrett, CEO</td>
<td>May 14, 2013</td>
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<tr>
<td>• Jeffrey Low, Chair, Board of Directors</td>
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<tr>
<td>Dr. Jake Thiessen</td>
<td>May 27, 2013; September 23, 2013</td>
</tr>
<tr>
<td>ORGANIZATION/INDIVIDUAL</td>
<td>DATE(S) OF APPEARANCE</td>
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</tr>
<tr>
<td>Windsor Regional Hospital/Hôtel-Dieu Grace Hospital</td>
<td></td>
</tr>
<tr>
<td>• Christine Donaldson, Regional Director, Pharmacy</td>
<td></td>
</tr>
<tr>
<td>• Dr. Gary Ing, Chief of Staff</td>
<td>April 22, 2013</td>
</tr>
<tr>
<td>• David Musyj, President and CEO</td>
<td></td>
</tr>
<tr>
<td>• Dr. Kenneth Schneider, Chief of Oncology</td>
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</tbody>
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APPENDIX C

Recommendations from Dr. Jake Thiessen’s
A Review of the Oncology Under-Dosing Incident

<table>
<thead>
<tr>
<th>Group Purchasing Organizations (GPOs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Notwithstanding the under-dosing incident, the continued use of Group Purchasing Organizations (GPOs) to negotiate vendor product preparation pharmaceutical services shall not be discouraged. However, improvements are needed in the GPO-based processes.</td>
</tr>
<tr>
<td>2. Every GPO shall review its procurement process to ensure that risk for patients is considered an essential evaluation and adjudication criterion when considering proposals.</td>
</tr>
<tr>
<td>3. Every GPO shall develop and adopt a standardized product and/or service specification description that outlines the requirements for contracted sterile or non-sterile pharmaceutical preparation services.</td>
</tr>
<tr>
<td>4. Annually in January, each GPO shall publicize information regarding the contracted pharmaceutical services provided by all its vendors.</td>
</tr>
<tr>
<td>5. Marchese Hospital Solutions (MHS) shall review and revise its product preparation processes to ensure that all its products meet the specifications required by professionals in treating patients effectively and safely.</td>
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<table>
<thead>
<tr>
<th>Manufacturing and Compounding</th>
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<tr>
<td>6. The Ontario College of Pharmacists (OCP) (and by extension, the National Association of Pharmacy Regulatory Authorities [NAPRA]) shall work quickly with Health Canada to define best practices and contemporary objective standards for non-sterile and sterile product preparation within a licensed pharmacy.</td>
</tr>
<tr>
<td>7. The OCP (and by extension, NAPRA) shall stipulate specialized electronic material records and label requirements for non-sterile and sterile product preparation within a licensed pharmacy.</td>
</tr>
<tr>
<td>8. The OCP (and by extension, NAPRA) shall consider a special designation and licence for any licensed pharmacy engaged in large volume non-sterile and sterile product preparation. Such pharmacies shall be inspected annually.</td>
</tr>
<tr>
<td>9. The OCP shall specify credentials beyond education and licensing for personnel engaged in non-sterile and sterile product preparation practices within a licensed pharmacy.</td>
</tr>
<tr>
<td>10. Health Canada shall license all enterprises that function beyond the product preparation permitted within a licensed pharmacy; that is, all product preparation enterprises not within a licensed pharmacy shall be licensed.</td>
</tr>
</tbody>
</table>

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78 Thiessen, A Review of the Oncology Under-Dosing Incident, pp. 2-3.
<table>
<thead>
<tr>
<th>Hospitals, Clinics and Associated Pharmacies</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. The Ontario Hospital Association (OHA) shall conduct a formal review/audit to determine the efficiency and traceability of computer-based clinic and hospital records for patients and their treatments, and report the findings to the MOHLTC.</td>
</tr>
<tr>
<td>12. The OCP shall license all pharmacies operating within Ontario's clinics or hospitals.</td>
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APPENDIX D

Letters to Ontario College of Pharmacists

October 31, 2013

Marshall Moleschi
Registrar
Ontario College of Pharmacists
483 Huron Street
Toronto, ON M5R 2R4

Dear Dr. Moleschi,

The Standing Committee on Social Policy is currently conducting a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

During the hearings the Committee heard testimony from a number of Pharmacists from Marchese Health Care, Medbuy Corporation and the purchasing hospitals involved. The Committee is concerned that the diluted chemotherapy treatments went unnoticed by all of the pharmacists directly involved, for an extended period of time (February 2012-March 2013) without one of them bringing the matter forward.

The Committee has asked me to bring this to the attention of the Ontario College of Pharmacists and for you to launch an investigation.

The Committee would appreciate a report with your decision and findings at your earliest convenience.

On behalf of the Committee, I thank you for your assistance in this matter. If you require any further information, please do not hesitate to contact the Clerk of the Committee, William Short at 416-325-3883 or at william_short@ontla.ola.org.

Sincerely,

Ernie Hardeman, MPP
Chair of the Committee
December 3, 2013

Marshall Moleschi
Registrar
Ontario College of Pharmacists
483 Huron Street
Toronto, ON M5R 2R4

Dear Dr. Moleschi,

Thank you for your letter dated November 14, 2013 in response to the Committee’s letter dated October 31, 2013, expressing concern that the diluted chemotherapy treatments went unnoticed by all of the pharmacists directly involved, for an extended period of time without one of them bringing the matter forward.

The Committee would like to follow up and seek clarification on what steps you plan to take not only to address this issue but to ensure it does not happen again. In particular, the Committee asks that you investigate: how this oversight occurred in the first place; why it went on for a long period of time; what are the consequences for such errors; and what changes will be made.

On behalf of the Committee, I thank you for your attention to this matter. If you require further information, please do not hesitate to contact the Clerk of the Committee, Valerie Quioc Lim at 416-325-7352 or at valerie_quioc@ontla.ola.org.

Sincerely,

Ernie Hardeman, MPP
Chair of the Committee
Email from Accreditation Canada

Requirements related to contractual relationships with GPOs and SSOs are captured in our Leadership Standards and Medication Management Standards. Below is a summary of the specific requirements in the Standards.

The Medication Management Standards focus on an inter-team approach to prevent and help reduce medication errors and near misses by addressing all aspects of the medication management process, from selection and preparation to administration of the medication and ongoing monitoring of clients. The Standards were recently revised in January 2013 under the guidance of a standards working group consisting of experts in the field from across Canada. The Standards were also circulated to stakeholders for broader feedback prior to release. The revised Standards apply to on-site surveys starting in January 2014.

One of the sections in the Medication Management Standards focuses on “Selecting and Procuring Medications”, including the following requirements:

- When selecting medications, the organization examines their packages and labels to identify any potential for confusion (9.1)
- The organization purchases commercially manufactured medications when available to minimize compounding (9.2)
- The pharmacy has a process to identify and resolve problems with medication shipments (9.5)
- The pharmacy has a process to retrieve medications that have been formally recalled or discontinued by Health Canada or the manufacturer (9.6)
- The organization has a process for selecting and procuring medication delivery devices (10.0)
- The organization reports labelling, packaging, and nomenclature problems on medications received from procurement (17.5)

In addition, the Medication Management Standards include the following requirements related to labelling, and monitoring the quality of contracted services:

- The organization labels all compounds and intravenous admixture containers with, at a minimum, information on the name of the medication, base solution, total amount of drug additives, and total volume of solution in the container (17.2)
- Where medication management processes are contracted to external providers, the organization establishes and maintains a contract with each provider that

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79 Email from Accreditation Canada, Ottawa to Researcher, Standing Committee on Social Policy, December 16, 2013.
requires consistent levels of quality and adherence to accepted standards of practice (27.2)

- Where medication management processes are contracted to external providers, the organization regularly monitors the quality of services provided (27.3)

- Further, the Leadership Standards include the following requirements related to selecting and monitoring the quality of contracted services:

- As part of [an] integrated risk management approach, the organization's leaders follow established policies and procedures for selecting and negotiating contracted services.

- Policies and procedures should include - selecting contracted organizations; negotiating the terms of the agreement; signing, reviewing and updating all contracts; and anticipating and addressing risks associated with contracted services.

- As part of [an] integrated risk management approach, the organization's leaders evaluate the quality of contracted services.
Appendix 3

MEDEC Position Paper – Third Party Review Process for Procurement
Third Party Review Process for Procurement in Ontario

BACKGROUND

In recent years, many physicians and healthcare institutions in Canada have turned to buying groups, group purchasing organizations, and shared services organizations, (collectively, “Health Care Procurement Organisations or HCPO’s”) to fulfill their procurement needs. According to the Broad Public Service Directive in Ontario, the purpose of the Directive for these organizations is:

1. To ensure that publicly funded goods and services, including construction, consulting services, and information technology are acquired by BPS organizations through a process that is open, fair, and transparent;
2. To outline responsibilities of BPS organizations throughout each stage of the procurement process; and
3. To ensure that procurement processes are managed consistently throughout the BPS.

Further to the purpose of the BPS Directives, the 5 Principles of the Directive are:

• Accountability
• Transparency
• Value for Money
• Quality Service Delivery
• Process Standardization

These goals are accomplished largely through the implementation of competitive procurement processes, such as issuing requests for proposals ("RFPs"), to which multiple vendors respond.

CURRENT ENVIRONMENT

Currently there is no third party mechanism in place to ensure that the purpose and principles of the Directive are complied with, which diminishes the effectiveness and original intent of the directives. When there is any issue or a challenge to the process or decisions of HCPO’s, suppliers must challenge the very organization that made the decision in the first place.

The benefits of having a third party process for resolving disputes regarding the procurement activities of HCPOs in the health care sector are:

• Improves accountability and transparency for procurement decisions and processes
• Maximize the value that HCPOs receive from the use of public funds
• Ensures a fair process for suppliers
• Improves patient care

The benefits of a third party review process are:

• Improves accountability and transparency for procurement decisions and processes
• Maximize the value that HCPOs receive from the use of public funds
• Ensures a fair process for suppliers
• Improves patient care

PROPOSAL

Through its Broader Public Sector Procurement Directive (the “Directive”), the Ontario government has demonstrated a commitment to improving accountability and transparency for procurement decisions and processes, and maximizing the value that broader public sector (“BPS”) organizations, including HCPOs, receive from the use of public funds. However, beyond providing that “[c]ompetitive procurement documents must outline bid dispute resolution procedures” the Directive provides little guidance on how BPS organizations are to be held accountable for their decisions.

A mechanism which allows stakeholders to challenge the actions taken by an HCPO would serve to instill the desired transparency and accountability into the decision-making process. An example of where such a mechanism can be seen in the Canadian International Trade Tribunal (“CITT”) which, through its Procurement Review Process, allows a potential supplier concerned about the propriety of a procurement process to submit a complaint and obtain redress. In this case, the CITT Procurement Review Process applies only to certain federal government procurements. The procurement decisions of HCPOs, which are typically funded by the provinces, are not subject to the purview of this process.

The CITT Procurement Review Process may be used as a best practice model to develop a legislatively-imposed dispute resolution process related to the procurement activities of HCPOs.

MEDEC recommends amending the Directive and its supporting documentation to provide for a specific process for resolving disputes regarding the procurement activities of HCPOs in the health care sector.

Appendix 1 (below) is a suggested dispute resolution procedure to be added to the Implementation Guidebook of the Directive. The suggested procedure provides a clear, consistent and fair process for resolving disputes regarding a HCPO’s procurement activities. Where applicable, this dispute resolution procedure should be included in procurement documents issued by HCPO’s.

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3. For more information, see http://www.citt.gc.ca/en/procurement.
Appendix 1 – Sample Bid Dispute Resolution Procedure

10.3.8 BID DISPUTE RESOLUTION

**Directive Mandatory Requirement #25: Bid Dispute Resolution**

Competitive procurement documents must outline bid dispute resolution procedures to ensure that any dispute is handled in an ethical, fair, reasonable and timely fashion. Bid dispute resolution procedures must comply with bid protest or dispute resolution procedures set out in the applicable trade agreements.

Organizations must establish dispute resolution procedures to address suppliers’ concerns related to any aspect of the procurement process.

The following dispute resolution procedure should be adhered to by Organizations to ensure the transparency and accountability of the Organization through the implementation of a clear, consistent and fair process for resolving disputes regarding an Organization’s Supply Chain Activities. Where applicable, this dispute resolution procedure should be included in Procurement Documents.

10.3.8.1 SUPPLIER REQUESTS FOR TRANSPARENCY

10.3.8.1.1 Supplier Requests for Transparency

Where an Organization is engaged in Supply Chain Activities, including, without limitation:

- a) informal supplier or product research;
- b) issuing a Request for Information ("RFI") or Request for Expression of Interest ("RFEI");
- c) issuing a Request for Supplier Qualification ("RFSQ");
- d) issuing a Request for Proposals ("RFP");
- e) receiving bids or proposals;
- f) evaluating bids or proposals;
- g) awarding a contract; or
- h) negotiating and executing an awarded contract;

A Supplier may make a written request for transparency with regard to:

- i) the interpretation of the any procurement documents, including, without limitation, an RFI, RFEI, RFSQ, or RFP (collectively, “Procurement Documents”) or any underlying contract or award; or
- ii) the way in which the procurement process has been managed (a "Request for Transparency").

10.3.8.1.2 Response Period

An Organization must respond to a Request for Transparency, in writing, within ten (10) days. Such response must constitute a good faith attempt to address the substance of the Request for Transparency with the aim of satisfactorily resolving the Supplier’s issue. Until the Organization has responded to the Request for Transparency, the timeline for responding to any outstanding Procurement Documents ceases to run.

10.3.8.2 DISCUSSION

10.3.8.2.1 Good Faith Discussions

Where the issue is not satisfactorily resolved through a Request for Transparency (a “Dispute”), each of the Supplier and the Organization (each a “Party”, and collectively the “Parties”) will nominate a representative (the “Nominee”) to engage in good faith discussions, with the aim of resolving the Dispute within thirty (30) days following the response to the Request for Transparency (the “Discussion Period”).

10.3.8.2.2 Remedies

The parties agree that in determining a resolution, the Nominees may consider, without limitation, such form of resolution as they consider reasonable in the circumstances including cancellation, amendment or postponement of the RFP or any underlying contract or award.

10.3.8.2.3 No Abuse of Process

The parties agree that this process will only be used as a method to resolve genuine issues in good faith, and not to undermine or abuse an Organization’s procurement process or to cause unnecessary delay to the award or implementation of a contract.

10.3.8.3 DETERMINATION BY UMPIRE

10.3.8.3.1 Appointment of Umpire

The Parties emphasize that they expect their Nominees to resolve the Dispute and that it would detract from the spirit of this process if the Nominees could not reach an agreement. However, in the event that, despite their best efforts to do so, the Nominees are unable to reach an agreement within the Discussion Period and such time period has not been further extended by the Nominees, then they shall unanimously name an independent third party (the “Umpire”) to resolve the Dispute.

10.3.8.3.2 Qualifications of Umpire

The Umpire shall be a lawyer with no less than five (5) years of experience in the area of procurement law or a person of such other qualifications mutually agreeable to the Parties. Without limiting the generality of the foregoing the Umpire shall be at arm’s length from the parties to the Dispute and shall not be a member of the audit or legal firm or firms who advise any Party to the Dispute, nor shall the Umpire be a person who otherwise is retained by such parties regularly. Should the Nominees be unable to agree on the name of the Umpire within thirty (30) days of the termination of the Discussion Period, then any Party to the Dispute will be free to request that the Arbitration and Mediation Institute of Canada (Toronto) (“AMIC”) do so on behalf of the Nominees and shall provide notice to the other Nominee that it is taking such action.

10.3.8.3.3 Submissions

Within thirty (30) days of the appointment of the Umpire (the “Submission Period”), each Party to the Dispute shall deliver to the Umpire (and to the other Party), copies of a submission which
states, in sufficient detail, the Dispute to be settled and the facts and arguments upon which the Party intends to rely and, if relevant, the relief it claims is fair and equitable as it relates to those areas in Dispute. All submissions shall be made on a without prejudice basis.

10.3.8.3.4 Hearings at Discretion of Umpire
The Umpire shall not be obliged to hear oral evidence or to hold a hearing if, in his or her discretion, he or she considers it to be unnecessary but he or she may make such decision only after receiving submissions on the question or upon the expiry of the Submission Period.

10.3.8.3.5 Decision
Within thirty (30) days after the Submission Period, the Umpire will deliver to each Party his or her decision in writing (the “Decision”), and, unless the Parties otherwise agree, the Umpire’s reasons will be set out in his or her Decision. The Umpire will send the Decision to the Parties as soon as practicable after the conclusion of the proceedings. The Decision shall be final and binding on the Parties to the Dispute.

10.3.8.3.6 Enforcement
The Parties to the Dispute consent to the Decision of the Umpire being entered in any court of competent jurisdiction for the purposes of enforcement.

10.3.8.3.7 Costs
The cost and expenses of the Umpire shall be borne equally by the Parties involved in the Dispute. Each party shall bear their own costs for preparing and submitting submissions regardless of the outcome of the decision of the Umpire.

10.3.8.4 CONFIDENTIALITY
10.3.8.4.1 Confidential Information
All meetings and hearings of or by the Nominees and the Umpire shall be in private and any party may be represented by legal counsel. This process and all other matters under this process, including, without limitation, all matters in dispute, all claims, submissions, evidence and findings, and the decision of any Umpire (collectively, the “Confidential Information”) shall be kept confidential by the parties, the Nominees and the Umpire, and no information regarding any of the foregoing will be released to any third party or otherwise made public without the written consent of all parties, except as otherwise contemplated herein and except for such information if:

a) the Confidential Information is, or becomes, publicly available;
b) the Confidential Information was known to the recipient prior to disclosure to it by the other party or is independently developed by the recipient; or
c) the other party has provided its prior written consent to such disclosure by the recipient; or
d) the Confidential Information is required to be disclosed by the recipient by the order of any Court or tribunal of competent jurisdiction.

10.3.8.4.2 Marking of Confidential Information
Each Party shall use all reasonable efforts to either mark its Confidential Information “Confidential” or “Proprietary” or ensure that it is accompanied by a notice indicating that such information is confidential. Verbal disclosure by a Party of its Confidential Information shall, if requested by the receiving Party, be followed by a written summary of the conversation marked “Confidential” and be delivered to the receiving Party within thirty (30) days of the conversation.

10.3.8.5 MISCELLANEOUS
10.3.8.5.1 No Impairment of Rights
This process does not limit or impair the rights of any Supplier to seek a review through other review processes or remedies of law through the judicial or other processes.

10.3.8.5.1 Extension of Term of Award
To the extent that the above-described dispute resolution process delays the implementation of a contract rightfully awarded to a Supplier, the term of the contract shall be automatically extended by the duration of such delay.

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.
Appendix 4

Duplication - Health Canada and ISO Requirements
Duplication of Health Canada Requirements and ISO Standards in Medical Device Procurement Practices

*This document has been compiled courtesy of the Regulatory Affairs; ISO Quality Systems Analyst and Contract Management individuals within Cook Medical Canada*

Introduction

Health Canada Mandate

Health Canada reviews medical devices to assess their safety, effectiveness and quality before being authorized for sale in Canada. Health Canada requires medical device manufacturers to use a quality system certificate as evidence of compliance to the appropriate regulatory quality system requirement. Health Canada will only accept quality system certificates that have been issued by special third party auditing organizations called Canadian Medical Devices Conformity Assessment System (CMDCAS) recognized registrars. The Medical Devices Regulations do not require importers or distributors of medical devices to have a registered quality system. The Medical Devices Regulations require class II, III and IV medical devices to be manufactured (class II) or designed and manufactured (class III & IV) under CAN/CSA ISO 13485:2003. There are no regulatory quality system requirements for class I medical devices. See Appendix 1 for a listing of requirements for each class of medical device.

ISO 13485:2003 Standard

Mandatory certification is required for manufacturers of class II, III, IV devices in Canada. This International Standard specifies requirements for a Quality Management System “where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to the medical devices and related services.” ISO 13485 certificates issued by a recognized registrar, are governed by Canadian Standards Association in liaison with Health Canada. See Appendix 2 for the sections listed in the ISO standard.

Given these Health Canada and ISO requirements it is redundant for the same information to be requested during the RFP process.

The Cost of Duplication

Duplication imposes added costs to the Health Care System. Resources have already been invested to obtain approvals from both Health Canada and ISO 13485:2003 Quality Systems, who have the mandate to review requirements. A burdensome volume of documentation is requested for commonly used devices in standard accepted practice and treatments. The average life span of a medical device is only 18 months. This lengthy process is an issue as are 5 year contract terms. In a 3 year period, over 9,500 new medical devices come to market.

References:

3. Medical Device Regulations SOR/98-282

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### RFP Requests Which Duplicate Health Canada Regulations and ISO 13485:2003 Requirements

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<tr>
<th>RFP Requests</th>
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<th>Requirements</th>
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<tbody>
<tr>
<td>1. Requiring Hard Copies of ISO 13485:2003 Certificates</td>
<td></td>
<td>It is mandatory that our manufacturers comply with ISO 13485:2003 in order to sell their devices anywhere in Canada.</td>
<td>Burdensome to provide this documentation when it is mandatory for medical device companies to comply with this standard. Medical device companies include a copy of the quality management system certificate in the Health Canada submission package; certifying that the quality management system under which the device is designed and manufactured satisfies CAN/CSA ISO 13485:2003, Medical devices - Quality management systems - Requirements for regulatory purposes.</td>
</tr>
<tr>
<td>2. Requiring Hard Copies of License Numbers</td>
<td>Health Canada section 26</td>
<td>“Subject to section 37, no person shall import or sell a class II, III or IV medical device unless the manufacturer of the device holds a license in respect of that device.”</td>
<td>License numbers are available on the Health Canada website. Hard copies of licenses are company confidential.</td>
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<td></td>
<td>HC section 36(1)</td>
<td>“If the Minister determines that a medical device in respect of which an application is submitted meets the safety and effectiveness requirements, the Minister shall (a) issue to the manufacturer of the device a medical device license, in the case of an application for a medical device license”</td>
<td></td>
</tr>
<tr>
<td>3. Requiring a Copy of the Establishment License</td>
<td>HC section 44(1)</td>
<td>“No person shall import or sell a medical device unless the person holds an establishment license”</td>
<td>The establishment number is available on the Health Canada website. The establishment license is company confidential.</td>
</tr>
<tr>
<td>4. Questioning Sterile Packaging</td>
<td>HC section 16</td>
<td>“The design, manufacture and packaging of a medical device”</td>
<td>Packaging design is developed and tested prior to device market.</td>
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**References:**
3. Medical Device Regulations SOR/98-282

**Updated Jan. 9, 2015**

**Company Confidential**
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| Delivery and if Product Packaging Is Tamper-Evident                         | ISO section 7.3.2.2         | shall minimize any risk to a patient, user or other person from reasonably foreseeable hazards, including: flammability or explosion, presence of a contaminant or chemical or microbial residue, radiation, electrical, mechanical or thermal hazards, and fluid leaking from or entering into the device. | approval. Health Canada reviews testing reports. Device is proven to be safe for transport and/or delivery. If the product is subject to a shelf-life, shelf-life testing will be completed. The method used, along with the storage conditions and the state of the product when tested are all examined.  
As per ISO standard, device planning takes into account the design of the product packaging. If the device requires special packaging (e.g., considerations related to sterility, humidity, light sensitivity, pressure or oxidative reaction under irradiation), evidence is provided that this has been addressed. Likewise, evidence is provided to demonstrate that the integrity of the device and the internal environment are maintained by the device packaging during handling, transport and storage. |
| ISO section 7.5.1                                                             |                             | Packaging, considers the packaging material, process conditions and anticipated storage and handling conditions during manufacturing, warehousing and distribution. The following should be considered: compatibility with device and packaging process, compatibility with the sterilization process, transportation hazard trials/shipping tests, microbial barrier properties of packaging materials for sterile devices, integrity of the primary container/package to prevent damage and to maintain sterility or cleanliness as required. |                                                                                                                                             |
| 5. Questioning Sterility Procedures and                                       | Health Canada section 17    | Mandates proper sterility procedures and parameters: “A medical device that is to be devices are tested for proper sterilization procedures and processes. Burdensome to provide”                                                                 |                                                                                                                                             |

References:
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<tr>
<td>Quality Assurance Parameters</td>
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<td>sold in a sterile condition shall be manufactured and sterilized under appropriately controlled conditions, and the sterilization method used shall be validated.”</td>
<td>again as HC examines this in detail upon application to market. Process validation data includes sterility test data, reference to a standardized test method and attestation or evidence of successful validation under real-life conditions under which the product is to be sterilized. Bioburden determination, culture media used, time and temperature of incubation, controls, number of samples examined and frequency of testing is also presented. A Sterility Assurance Level (SAL) of 10⁻⁶ is generally required. The manufacturer should also have a process in place to monitor bioburden levels on a regular basis to confirm that the sterilization method remains valid.</td>
</tr>
<tr>
<td>Health Canada section 32(3)(e)</td>
<td>“in the case of a device to be sold in a sterile condition, a description of the sterilization method used”</td>
<td></td>
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<tr>
<td>ISO sections 7.5.1.3 and 7.5.2.2</td>
<td>Particular requirements for sterile medical devices; the organization shall maintain records of the process parameters for the sterilization process which was used for each sterilization batch. The organization shall establish documented procedures for the validation of sterilization processes. Sterilization processes shall be validated prior to initial use.</td>
<td>Medical device companies must have supporting documentation for procedures and parameters for sterile devices and sterilization process. Where the device is supplied sterile, detailed information of the initial sterilization validation including bioburden testing, pyrogen testing, testing for sterilant residues (if applicable) and packaging validation is provided. Typically, the detailed validation information should include the method used, sterility assurance level attained, standards applied, the sterilization protocol developed in accordance with those standards, and a summary of results.</td>
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6. Questioning

| HC section | “The information required” | Labeling regulations list all the |

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<tr>
<td>Visibility of Information on Packaging</td>
<td>21(2)</td>
<td>pursuant to subsection (1) shall be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user.”</td>
<td>information required to be present on the device label, inside and outside packaging.</td>
</tr>
<tr>
<td>7. Detailed Information for Product Storage</td>
<td>Provided in HC submissions, as well as on labelling of device package.</td>
<td>Evidence is provided that the internal environment can be maintained by the device packaging during handling, transport and storage. Shelf-life testing along with the storage conditions are provided to Health Canada during the submission process.</td>
<td></td>
</tr>
<tr>
<td>ISO section 7.5.5</td>
<td>Preservation of Product; “establishing documented procedures to preserve product conformity during internal processing and delivery (ex: ID, handling, packaging, storage, protection)”</td>
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<td></td>
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<tr>
<td>8. Safety Documentation and Relevant Testing Mechanisms</td>
<td>HC section 32(2)(c)</td>
<td>Mandates for a class II device that an attestation be provided by a senior official of the manufacturer that the manufacturer has objective evidence to establish that the device meets the safety and effectiveness requirements.</td>
<td>Complete physical or mechanical bench test data is provided. Reports cover the objectives, methodology, results and manufacturer’s conclusions of all physical studies of the device and its components. Acceptance criteria along with a rationale for this criteria is included along with the results of testing.</td>
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<tr>
<td></td>
<td>HC section 32(3)(f) and (i)</td>
<td>For a class III device mandates a summary of all studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness requirements, and the conclusions drawn from those studies; as well as a bibliography of all published reports dealing with the use, safety and effectiveness of the device.</td>
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<td></td>
<td>HC section 32(4)(d), (i)</td>
<td>Class IV devices require a risk assessment with an analysis and evaluation of the risks, risk reduction measures adopted to satisfy the safety and effectiveness requirements;</td>
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<tr>
<td>9. Standards We Adhere To (ex: ASTM, CSA, CAG, CIRA, and ORNAC)</td>
<td>HC sections 32(3)(d), (4)(h)</td>
<td>Require we have a list of standards provided as part of licensing process; “a list of the standards complied with in the design and manufacture of the device to satisfy the safety and effectiveness requirements”.</td>
<td>The list of standards applied, in whole or in part, in the design and manufacture of the device are provided to Health Canada. These standards may be international or national.</td>
</tr>
<tr>
<td>10. ISO 10993 Biological Evaluation of Medical Devices/ Biocompatibility</td>
<td>Provided in HC submissions within the safety and effectiveness studies, preclinical/biocompatibility section.</td>
<td>Tests are conducted on samples from the final product after all manufacturing and processing has been completed. Summaries should cover the tests conducted, standards applied, test methodology; pass fail criteria chosen with justification, and a summary of the results and conclusions drawn.</td>
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</tr>
<tr>
<td>11. ISO 11070:1999 Friction Resistant Coating</td>
<td>Standards listing supplied in submission to Health Canada.</td>
<td>Tests are conducted on samples from the final product after all manufacturing and processing has been completed. Summaries should cover the tests conducted, standards applied, test methodology; pass fail criteria chosen with justification, and a summary of the results and conclusions drawn.</td>
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<tr>
<td>13. External Packaging Information (ex: name, description, size, lot number, code, unit, multi/single use)</td>
<td>HC sections 21(1), (2)</td>
<td>HC sections 21(1) and 21(2) list the information required for proper labelling of a medical device.</td>
<td>Copies of all labelling, package inserts, product brochures and file cards to be used in connection with the device, as well as copies of information and instructions for use for the practitioner and/or the patient is included in the</td>
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<td></td>
<td>ISO section 7.3.2.3</td>
<td>Labelling; the content of labels may be specified in regulatory requirements, general</td>
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<tr>
<td>Health Canada section 23(1)</td>
<td>Bilingual instructions - Subject to subsection (3), the information required by subsection 21(1) shall, as a minimum, be in either English or French.</td>
<td>Not mandatory to provide in both English and French unless sold directly to the general public.</td>
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<tr>
<td>Health Canada section 16</td>
<td>Resists fluid penetration – “The design, manufacture and packaging of a medical device shall minimize any risk to a patient, user or other person from reasonably foreseeable hazards, including: (e) fluid leaking from or entering into the device.”</td>
<td>Reviewed during product design and development stages.</td>
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<tr>
<td>Health Canada section 21(1)(e)</td>
<td>Accurate identification of contents – “if the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as the size, net weight, length, volume or number of units”</td>
<td>This is mandatory compliance as per labelling guidance documents.</td>
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<tr>
<td>Health Canada section 16</td>
<td>Opens with ease - “The design, manufacture and packaging of a medical device</td>
<td>Reviewed during product design and development stages.</td>
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<td>shall minimize any risk to a patient, user or other person from reasonably foreseeable hazards.</td>
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<td></td>
<td>Dispenses appropriately - “The design, manufacture and packaging of a medical device shall minimize any risk to a patient, user or other person from reasonably foreseeable hazards.</td>
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<td>Tamper resistant – “The design, manufacture and packaging of a medical device shall minimize any risk to a patient, user or other person from reasonably foreseeable hazards, including: (a) flammability or explosion, (b) presence of a contaminant or chemical or microbial residue, (c) radiation, (d) electrical, mechanical or thermal hazards, and (e) fluid leaking from or entering into the device.</td>
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<tr>
<td>Health Canada section 13</td>
<td></td>
<td>Withstands repeated handling - “During the projected useful life of a medical device, its characteristics and performance shall not deteriorate under normal use to such a degree that the health or safety of a patient, user or other person is adversely affected.”</td>
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<tr>
<td>ISO section 7.5.5</td>
<td></td>
<td>Preservation of Product; “establishing documented procedures to preserve product conformity during internal processing and delivery (ex: ID, handling, packaging, storage, protection).”</td>
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<tr>
<td>15. Country of Manufacture</td>
<td>HC section 21(1)(b)</td>
<td>Mandates that the company provide the name and address of the manufacturer.</td>
<td>The medical device submission to HC will identify the sites where design and manufacturing activities are performed. If QMS certificates exist for these sites, they are included in the application.</td>
</tr>
<tr>
<td>16. Product Composition</td>
<td>HC section 32(4)(a), (b)</td>
<td>For class III and IV devices; mandate a description of the device and of the materials used in its manufacture and packaging, as well as a description of the features of the device that permit it used for medical conditions, purposes and uses for which it is manufactured, sold or represented.</td>
<td>A list is provided in the application of the features, dimensions and performance attributes of the medical device, its variants and accessories, that would typically appear in the product specification made available to the end user, e.g. in brochures and catalogues.</td>
</tr>
<tr>
<td>17. List All Equipment with Which Your Products Are Compatible and Provide Validation</td>
<td>HC section 15</td>
<td>Reasonable measures shall be taken to ensure that every material used in the manufacture of a medical device shall be compatible with every other material with which it interacts and with material that may come into contact with it in normal use, and shall not pose any undue risk to a patient, user or other person.</td>
<td>A description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the product are provided in the application package to Health Canada.</td>
</tr>
<tr>
<td>18. How Product Material and/or Composition Contribute To Functionality</td>
<td>ISO section 7.3.4</td>
<td>Design and Development Review; at suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements. a) To evaluate the ability of the results of design and development to meet requirements b) To identify any problems and propose necessary actions</td>
<td>The features that enable the device to be used for the medical conditions and purposes for which it is manufactured, sold or represented by the manufacturer are described in the submission to HC. A brief description of the underlying science/technology, design concepts, and/or theoretical principles supporting the device's function are provided. As well a description of all functional</td>
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<tbody>
<tr>
<td>19. Describe Any Features or Benefits That Are Unique To Your Product(s) That Contribute To Safety</td>
<td>Provided in submission to Health Canada.</td>
<td>Discussed in detail in the design philosophy section. Includes a brief description of the principles and theories that enable the device to be used for the medical conditions and purposes for which it is manufactured, sold or represented. Unique or novel design features are highlighted and related literature provided in the submission.</td>
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</table>
| 20. Discuss Third Party Product Evaluations and/or Conversions (Canadian Experience Preferred) | A bibliography of all published reports dealing with the use, safety and effectiveness of the device. | A bibliography or list of references of all relevant published literature dealing with the use, safety and effectiveness and the indications for use of the subject device is provided in the Clinical Evidence Report in the submission to HC. | Design and development validation; to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. Validation shall be completed prior to the delivery or implementation of the product.  
- a critical analysis of relevant literature  
- historical evidence that similar designs and/or materials are clinically safe  
- a clinical investigation |
| 21. Discuss Contraindications and/or Precautions | Provided in the intended use labeling of the device whereby it states any contraindications/precautions if present. | Contraindications for the device are to be stated as presented in the labelling. The statement of contraindications should specify the clinical conditions of a patient that would make use of the device inadvisable. | |
| 22. Product(s) Expiry Date and/or Shelf Life | The expiry date of the device, if the device has one, to be determined by the | Tests that validate the stability and continued functionality of the product, including chemical and | |

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<td>manufacturer on the basis of the component that has the shortest projected useful life.</td>
<td>physical properties, and critical performance characteristics under the storage conditions specified are performed. The method used is provided along with the storage conditions used and the state of the product when tested. Devices containing materials of unknown stability should have real-time data.</td>
</tr>
<tr>
<td>ISO 13485:2003 Section 7.1.3</td>
<td>Lifetime of the medical device a) shelf life of the medical device, b) expiry date for medical device or components which are subject to degradation over time, c) number of cycles or periods of use of the medical device, based on life testing of the medical device, d) anticipated material degradation, e) stability of packaging etc.</td>
<td>ISO Shelf Life Validation of the Packaging; If the device requires special packaging, evidence should be provided that this has been addressed. Likewise, evidence should be provided to demonstrate that the integrity of the device and the internal environment can be maintained by the device packaging during handling, transport and storage.</td>
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<tr>
<td>23. Indication for Use on Paediatric Patients</td>
<td>HC section 21(1)(h)</td>
<td>Found in Instructions for Use, “unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, including the performance specifications of the device if those specifications are necessary for proper use”.</td>
<td>The statement of indications for use describes the diseases or conditions the device will diagnose, treat, prevent or mitigate, and the clinical condition of the patient under which use is recommended. It will specify the patient population for which use of the device is indicated.</td>
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<tr>
<td>24. Clinical Evidence Report</td>
<td>HC section 32(4)(i)</td>
<td>Detailed information on all studies on which manufacturer relies to ensure device meets the safety and effectiveness requirements.</td>
<td>A clinical evaluation is done on available, relevant clinical data from published sources, or device-related investigations. If a clinical history has been well established with a given device technology, evidence may be provided in the form of a literature review of relevant publications in the peer-reviewed scientific literature.</td>
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</table>

References:
3. Medical Device Regulations SOR/98-282

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<table>
<thead>
<tr>
<th>RFP Requests</th>
<th>Health Canada/ISO Sections</th>
<th>Requirements</th>
<th>Explanation</th>
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<td>be completed prior to the delivery or implementation of the product.</td>
<td>Clinical evidence in the form of device-specific clinical investigations conducted in Canada or other countries are provided. Reports cover the objectives, methodology and results. The conclusions on the outcome of the clinical investigations are included. Both statistical and clinical significance is critically analyzed.</td>
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<td>25. Bench testing (kink resistance, etc.)</td>
<td>HC section 32(4)(i)</td>
<td>Detailed information on all studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness requirements, including (i) pre-clinical and clinical studies.</td>
<td>Detailed test reports are provided, as well as a summary of each test conducted and the conclusions drawn from those tests. With context relating to why the tests are being presented and the risks they address.</td>
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<td>ISO section 7.3.5</td>
<td>Design and development verification; Necessary to ensure that the design and development outputs conform to specified requirements.</td>
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<td>• tests (e.g. bench tests, laboratory analyses)</td>
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<td>• alternative calculations</td>
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<td>• comparison with proven design</td>
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<td>• document reviews</td>
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<td>26. Provide Information on Product Adverse Events, Alerts and Recalls within the Last 36 Months</td>
<td>HC section 32(4)(c)</td>
<td>Provided in HC submission for class III and class IV devices.</td>
<td>A summary of the marketing history is required. The manufacturer must provide a list of countries or regions, where the subject device is currently being sold and the total number of units sold. A summary is included of each reported incident and details of any recalls of the device in countries where the device has been sold. Estimated rates of occurrence of reported incidents are also provided.</td>
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<td>A list of the countries other than Canada where the device has been sold, the total number of units sold in those countries, and a summary of any reported problems with the device and any recalls of the device in those countries.</td>
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</table>

References:
3. Medical Device Regulations SOR/98-282
Appendix 1 - Health Canada Requirements by Risk Class (Non-IVDD)

Class I Medical Device
This is the lowest risk class. Must meet safety and effectiveness requirements. No license required. Proper labeling required.

Class II Medical Device
Must be licensed by Health Canada.

1. Application contains name of device, class, identifier, name and address of manufacturer, name and address of establishment where device is being manufactured, the description of the medical conditions, purposes and uses for which the device is manufactured.
2. A list of standards complied in the manufacture of the device to satisfy the safety and effectiveness requirements, as well as an attestation that the device meets safety and effectiveness.
3. A label is provided as well as a copy of the ISO 13485:2003 certificate.

Class III Medical Device
In addition to class II information, Health Canada also requests:

1. A description of the device and of the materials used in its manufacture and packaging.
2. A description of the features of the device that permit it to be used for the medical conditions purposes and uses for which it is manufactured, sold or represented.
3. A list of the countries other than Canada where the device has been sold, the total number of units sold in those countries, and a summary of any reported problems with the device and any recalls of the device in those countries.
4. In the case of a device to be sold in a sterile condition, a description of the sterilization method used.
5. A summary of all studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness requirements, and the conclusions drawn from those studies by the manufacturer.
6. A bibliography of all published reports dealing with the use, safety and effectiveness of the device.

Class IV Medical Device
This is the highest risk class. In addition to class III information, Health Canada also requests:

1. A risk assessment comprising an analysis and evaluation of the risks, and the risk reduction measures adopted to satisfy the safety and effectiveness requirements.
2. A quality plan setting out the specific quality practices, resources and sequence of activities relevant to the device.
3. The specifications of the materials used in the manufacture and packaging of the device.
4. The manufacturing process of the device.
5. Detailed information on all studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness requirements, including: pre-clinical and clinical studies, process validation studies (if appropriate), software validation studies, and literature studies.
6. In the case of a medical device other than an in vitro diagnostic device, manufactured from or incorporating animal or human tissue or their derivative, objective evidence of the biological safety of the device.
7. A summary of the studies and the conclusions drawn from those studies by the manufacturer.

References:
3. Medical Device Regulations SOR/98-282
Appendix 2 - ISO 13485:2003 Sections

1. Scope
2. Normative Reference
3. Terms and Definitions
4. Quality Management System
   o General requirements
   o Documentation requirements
5. Management Responsibility
   o Management commitment
   o Customer focus
   o Quality policy
   o Planning
   o Responsibility, authority and communication
   o Management review
6. Resource Management
   o Provision of resources
   o Human resources
   o Infrastructure
   o Work environment
7. Product Realization
   o Planning of product realization
   o Customer-related processes
   o Design and development
   o Purchasing
   o Product and service provision
   o Control of monitoring and measuring devices
8. Measurement, Analysis and Improvement
   o General
   o Monitoring and measurement
   o Control of nonconforming product
   o Analysis of data
   o Improvement

References:
3. Medical Device Regulations SOR/98-282
Appendix 5

HSCN Common Tendering and Contracting Templates*

*(due to the extensive size of the documents, please see http://www.hscn.org/ctc-templates.aspx to gain access to these documents)
Appendix 6

HSCN Innovation Procurement Toolkit*

*(due to the extensive size of the documents, please see http://www.hscn.org/innovation-procurement-toolkit-.aspx to gain access to these documents)
Appendix 7

MEDEC Code of Conduct
The Goal Of The MEDEC Code

1.1 Canada’s Medical Technology Companies (“MEDEC”) is dedicated to advancing healthcare through innovative technologies, devices and diagnostics (“technologies”). MEDEC believes that access to high quality, cost-effective healthcare technology is paramount to the improvement of patient care. MEDEC represents companies that design, develop, manufacture and market medical technologies and related services used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition.

1.2 Medical technologies are often highly dependent upon “hands on” Healthcare Professional interaction from beginning to end—unlike drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means. For example, implantable medical technologies are often placed in the human body to replace or strengthen a body part. Surgical medical technologies often serve as extensions of a physician’s hands. In other circumstances, medical technologies are non-invasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Healthcare Professionals. Some medical technologies work synergistically with other technologies, or are paired with other products that deploy technologies in the safest and most effective manner. Many medical technologies require technical support during and after deployment.

1.3 In pursuing this mission, MEDEC member companies (“Companies”) recognize that adherence to ethical standards and compliance with applicable laws is critical to the Canadian medical technology industry’s ability to continue its collaboration with Healthcare Professionals. MEDEC member companies comply with applicable regulatory requirements, including those pertaining to the Health Canada Medical Devices Special Access Programme. Further to the requirements of the Regulations, member companies are prohibited from promoting the sale of unlicensed devices. Where a physician has expressed their intent to submit a Special Access application, member companies can supply the information necessary to support the application in direct response to questions from the physician, but may not facilitate the application beyond the provision of information considered appropriate under the rules of the Program.

1.4 Companies encourage ethical business practices and socially responsible industry conduct related to their interactions with Healthcare Professionals and Government Officials.

1.5 Companies also respect the obligation of Healthcare Professionals to make independent decisions regarding Company products. MEDEC supports and respects the guidelines and policies established by professional societies or organizations that outline the obligations of the profession, while interacting with the Canadian medical technology industry.
1.6 MEDEC has revised and restated its 2005, 2010 and 2012 versions of this Code of Conduct. The 2015 version recognizes the changing business environment in Canada and globally. It also recognizes that healthcare regimes are governed by different laws, policies and practices. The 2015 MEDEC Code of Conduct represents a solid framework for the Canadian marketplace. This Code is intended for interactions with Healthcare Professionals and Government Officials and includes, but is not limited to, those individuals or entities that purchase, lease, recommend, use, train, arrange for the purchase or lease of, or prescribe Companies’ medical technology products in Canada.¹

All terms in this Code of Conduct are defined in the Glossary.

2 Scope Of The MEDEC Code

2.1 There are many forms of interactions between Companies and Healthcare Professionals that advance medical science or improve patient care, including:

2.1.1. Advancement of Medical Technology. Developing cutting-edge medical technology and improving existing products are collaborative processes between Companies and Healthcare Professionals. Innovation and creativity are essential to the development and evolution of medical technologies, often occurring outside the laboratories of medical technology companies. Heart valves, orthopaedic implants, cardiac rhythm devices, surgical tools and infusion pumps are just a few examples of the array of complex medical technologies developed through research collaborations and consulting relationships between Healthcare Professionals and Companies.

2.1.2. Safe and Effective Use of Medical Technology. The safe and effective use of sophisticated electronic, in vitro diagnostic, surgical or other medical technology often requires Companies to offer Healthcare Professionals appropriate instruction, 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 technology.

2.2 MEDEC recognizes that Companies may interact with Healthcare Professionals or Government Officials for many legitimate objectives other than selling, leasing, recommending, arranging for the sale or lease of, or prescribing products, 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 Healthcare Professionals or Government Officials not specifically addressed in this Code, should be made in light of the following principle: Companies shall ensure ethical business practices and socially responsible industry conduct and shall not use any unlawful inducement in order to sell, lease, recommend, or arrange for the sale, lease, or prescription of their products.

3 Compliance with the MEDEC Code of Conduct

The MEDEC Code of Conduct applies to all MEDEC member companies. Non-member companies may use the MEDEC Code as guidance in their Company’s interaction with Healthcare Professionals or Government Officials.

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

¹ The MEDEC Code of Conduct will be a “living” document, reviewed by the MEDEC Code of Conduct Committee annually to ensure the Code is aligned with the business environment.
with respect to their interactions with Healthcare Professionals or Government Officials related to medical technologies. The main intent of a compliance program is to ensure that there is not any “undue influence” on a sale or transaction with a Healthcare Professional or Government Official.

Companies are strongly encouraged to follow the seven elements of an effective compliance program, appropriately tailored for each Company, namely:

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

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

3.1 Certification
MEDEC 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 MEDEC 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 MEDEC Code of Conduct logo when responding to customer procurement requests. MEDEC will encourage Group Purchasing Organizations, hospitals and other customers generally to look for the MEDEC certification when reviewing procurement response submissions.

3.2 Violations Review Committee
Companies are encouraged to report potential Code violations to the MEDEC Code of Conduct Violations Review Committee. The Violations Review Committee will be staffed by three MEDEC members appointed by the MEDEC Board who are “Code Certified”. Companies must fully cooperate with the Violations Review Committee during its review and are expected to abide by its recommendations. A Company’s failure to abide by the Violations Review Committee’s recommendations may result in a loss of “Code Certification”. The primary goal of the Violations Review Committee is to eliminate confusion with respect to Code interpretation and ensure a level playing field among Companies. The Violations Review Committee’s interpretations of the Code’s applicability to certain fact situations may be published to Companies in an anonymized basis for educational purposes, such as in a Code FAQ document.

4 Company-Conducted Product Training and Education
MEDEC recognizes the essential commitment that Companies make to provide Healthcare Professionals or Government Officials with appropriate product education and training. Historically, both industry and Healthcare Professionals or Government Officials have worked collaboratively in providing education and training on medical technologies and therapies in order to improve the health of patients. Companies have a responsibility to make product education and training available to Healthcare Professionals, a practice that is strongly encouraged. However, Companies also recognize the need for Healthcare Professionals to preserve the freedom of the medical profession and maintain independence in ongoing education and assessment of Companies’ products and services.
4.1 When providing these programs and activities, Companies should adhere to the following:

- Companies should ensure that the primary purpose of the program is to address the educational/training needs of the Healthcare Professionals. If meals and refreshments are provided, they should be modest in value. Activities primarily promotional in nature should not be considered as educational/training programs.

- 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 Healthcare Professionals.

- Companies are not permitted to facilitate or pay for the meals, refreshments, travel, lodging or other expenses of guests of Healthcare Professionals or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.

5 Third-Party Educational Conferences

Bona fide independent, educational, scientific or policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective healthcare. These typically include conferences sponsored by national, regional or specialty medical associations or societies, conferences organized by accredited continuing medical education providers. All third-party education conference decisions 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. Companies may support these conferences in various ways:

5.1 Conference Sponsorships. Companies may provide conference sponsorships when the event is primarily dedicated to promoting objective scientific and educational activities and discourse. Such sponsorships may either be (a) provided to the conference sponsor to reduce the overall conference costs; or, (b) provided to institutions or relevant organizations to allow attendance by Healthcare Professionals to support professional development, in which case the institution, organization or the conference sponsor selects the attending Healthcare Professionals. Such sponsorships should be paid only to organizations with a genuine educational purpose or function and may be used only to reimburse the legitimate expenses for bona fide educational activities. Such sponsorships also should be consistent with relevant guidelines established by professional societies or organizations. The conference sponsor should be responsible for, and control the selection of, program content, faculty, educational methods and materials.

5.2 Direct Support of HCPs. Companies may provide direct support for reasonable expenses (travel, modest meals, accommodation, and registration) to Healthcare Professionals for professional development at third-party educational conferences when appropriate. Selection of HCPs should be done in an objective and transparent manner.

5.3 Meals and Refreshments. 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 all Healthcare Professional attendees, but only if it is provided in a manner that is also consistent with the sponsor's guidelines. Any meals and refreshments should be modest in value.
5.4 **Faculty Expenses.** Companies may make grants directly to conference organizer for reasonable honoraria, travel, lodging and modest meals for Healthcare Professionals who are *bona fide* conference faculty members.

5.5 **Satellite Symposiums.** Companies may sponsor satellite symposiums at third party conferences and provide presentations on subjects 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 events and be responsible for faculty selection. Company support for such events must be disclosed in all materials relating to the satellite event.

5.6 **Advertisements and Demonstration.** Companies may purchase advertisements and lease booth space for Company displays at conferences.

6 **Sales, Promotional and Business Meetings**

It is appropriate for Companies to conduct sales, promotional and other business meetings with Healthcare Professionals or Government Officials to discuss, for example, product features, contract negotiations and sales terms, insofar as the relationship does not impede on the Healthcare Professional’s or Government Official’s ability to maintain professional autonomy and independence. Such meetings should occur at or close to the Healthcare Professional’s or Government Official’s place of business. It is appropriate for Companies to pay for occasional modest meals and refreshments for Healthcare Professional or Government Official attendees in an environment that is conducive to the exchange of information. Where plant tours or demonstrations of non-portable equipment are necessary, it is appropriate to pay for reasonable travel costs of attendees. However, it is not appropriate to facilitate or pay for meals, refreshments, travel, lodging or other expenses of guests of Healthcare Professionals or Government Officials or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

7 **Arrangements with Consultants**

Many Healthcare Professionals and Government Officials serve as consultants to Companies providing valuable *bona fide* consulting services, including research, participation on advisory boards, presentations at Company-sponsored training and product collaboration. It is appropriate to provide Healthcare Professionals and Government Officials with reasonable compensation for performing these services. The following factors support the existence of a *bona fide* consulting arrangement between Companies and Healthcare Professionals or Government Officials:

- All consultancy agreements should have full transparency and HCPs should notify their employer.
- Company consulting arrangements should be written, signed by the parties and specify all services to be provided.
- Compensation paid to consultants should be consistent with fair market value for the services provided.
- Consulting agreements should be entered into only where a documented legitimate need and purpose for the services is identified in advance.
- Selection of consultants should be on the basis of the consultant’s qualifications and expertise to address the identified purpose and should not be related to the volume or value of business generated by the consultant.
- 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 consultants in carrying out the subject of the consulting arrangement, including reasonable and actual travel, modest meals and lodging costs incurred by consultants attending meetings with, or on behalf of, Companies.

• When a Company contracts with a consultant for research services, there should be a written research protocol.

• Government officials may be brought in as consultants and their employer should be notified.

### Gifts

#### 8.1

Except in very few well defined situations below, Companies must not provide gifts to Healthcare Professionals or Government Officials. The only acceptable gifts that can be provided must be occasional and relate to the Healthcare Professional’s practice, benefit patients or serve a genuine educational function, and must not be of a personal nature. Some examples of gifts allowed are medical textbooks or surgical and anatomical models, and any such gifts from a company may not exceed a fair market value of $100 CDN for any one instance.

#### 8.2

Companies may occasionally give Healthcare Professionals or Government Officials items of minimal value (having a fair market value of $10.00 CDN or less) as long as such are within the permitted categories above. Some examples are pens and notepads in the course of a business presentation or training. Gifts must not be given in the form of cash or cash equivalents (i.e., gift cards or gift certificates); must be recorded accurately; and must be provided in connection with a normal business relationship, without the expectation of reciprocity.

#### 8.3

It is not considered appropriate to give gifts to a Healthcare Professional or Government Official for their significant life events such as a marriage, birth or birthday. 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 the maximum fair market value limit of $100 CDN or less.

### Grants and Charitable Donations

Companies may make educational and research grants and charitable donations for philanthropic purposes. It is not appropriate for Companies to provide grants and donations for the purpose of unlawfully inducing Healthcare Professionals or Government Officials to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of Companies’ products. It is not allowable to provide a grant or donation directly to an individual Healthcare Professional or Government Official except where allowable in Section 5. All grants and donations must be provided directly to the Requesting Organization. All grant and donation decisions 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. Companies should implement appropriate measures to ensure that such grants or donations are not employed as an unlawful inducement. In addition, grant and donation decisions should be made without the control or influence of the sales organization and be appropriately documented. This section does not apply to Education and Research Funding provided as a Contract Value Add. These are covered in Section 10.

#### 9.1 Educational Grants

Educational Grants in accordance with Section 5, may be provided to educational institutions, professional organizations, and public healthcare institutions in support of bona fide continuing medical education programs, grand rounds, patient education and public education as long as all requirements of this Section are met. The Requesting Organization is responsible for controlling content, materials, budget, and selection of faculty. Educational Grants cannot be provided to Medical Practices or private healthcare insti-
tutions and cannot be used for recreation or entertainment or for programs in which the majority of content is not educational. Educational Grants can be monetary or medical technology, however, medical technology that is intended to be multi-use can only be provided as a loaned grant specifically for the requested program.

9.2 Research Grants
Research Grants may be provided to research institutions for purposes such as supporting genuine independent medical research for the advancement of medical science, or the improvement of healthcare delivery and increased patient access to healthcare technology. Research Grants must have scientific merit, 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 may not be linked, directly or indirectly, to the purchase of medical technology from the granting organization.

9.3 Charitable Donations
Companies may make monetary or Medical Technology donations for charitable purposes such as supporting patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Donations should be made only to organizations. Such organizations may include hospital foundations but do not include Healthcare facilities. 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 through a charitable organization. Charitable donations should not be made in response to a request by a Healthcare Professional or Government Official unless the Healthcare Professional or Government Official is an officer or employee of the organization and submits a written request on behalf of the organization.

10 Request for Proposals (RFP) and Tenders
10.1 Industry will follow all applicable conduct requirements in an RFP.

10.2 It is not unlawful for healthcare facilities to request “value added” items, grants or donations from Companies in conjunction with an RFP or tender process. Therefore “value added” requests are not unlawful inducements. However, MEDEC does not consider all “value added” requests as procurement best practice, unless the “value add” relates to the product and services requested in the RFP and are clearly defined (documented) within the RFP document.

11 Entertainment and Recreation
It is not appropriate for Companies to provide or pay for “Entertainment” for Healthcare Professionals or Government Officials regardless of whether the Healthcare Professional or Government Official is a consultant, speaker or otherwise.

12 Meals and Travel
Modest and reasonable meals and travel may be provided to Healthcare Professionals or Government Officials as an occasional business courtesy when part of a bona fide exchange of scientific, educational or business information. The time, duration of meals, and the venue in which they are provided should always be subordinate to the business purpose. Modest travel expenses are generally defined as economy class with exceptions permissible for legitimate reasons. It is not appropriate to provide meals or travel to spouses or guests of Healthcare Professionals or Government Officials or for any other person without a bona fide professional interest in the event.

This similarly applies to meals and travel in the following sections: 4. Company Conducted Prod-

### Product Evaluations

Product evaluations are defined as situations where Companies leave products and services for use for a limited time by Healthcare organizations free of charge.

In accordance with procurement policies or guidelines of the Healthcare Professional's organization, companies may provide products to Healthcare Professionals, at no charge, as part of the sales and customer evaluation processes.

- Product evaluation purposes in the interests of a potential customer in order to ensure that the potential customer's requirements are satisfied;

The following are required to be in place at the start of the evaluation period:

- The length of the loan must be known and limited to a reasonable evaluation period.
- The arrangement must be documented 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 influence an RFP.

### On-Site Product Demonstrations

On-site demonstrations are situations where Healthcare organizations utilize or observe equipment in their own clinical environment on a trial basis in the presence of a Company as part of the equipment selection process. The equipment remains in the possession of the Company over the course of the demonstration. The Company must assess if providing an on-site demonstration is appropriate in each circumstance.

Prior to the start of the on-site demonstration, the arrangement must be documented between the Healthcare organization and the Company which will contain the details and purpose of the demonstration, including the duration of the demonstration, the equipment and the scope of the on-site demonstration.

Upon the conclusion of the demonstration, the equipment should be removed by the Company, or stored at the Healthcare organization's location in a manner so that it cannot be utilized without the presence of the Company.

### Site Visits

Where site visits to clinical or manufacturing sites are necessary in order to evaluate products, Companies may fund reasonable expenses which are in line with this code and the member organization's travel policies for the visit 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 equipment.

Please reference the MEDEC Medical Imaging Staging an Effective Site Visit Guidance Document.
Third Party Intermediaries

In many instances Medical Device & Technology companies engage third party intermediaries (TPI) for the commercialization, distribution or sale of products and services to Healthcare Professional (HCP). Such entities may fall under the description of distributors, agents, subagents, wholesalers, brokers or independent sales agents. [See glossary for definition.]

Companies are liable for actions and activities of such third party intermediaries. Therefore, special attention should be given to ensure that TPIs undergo a full due diligence prior to retaining such third parties. Due diligence needs to be updated on a regular basis (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.

MEDEC emphasizes that it is the responsibility of each Company to train TPIs on the various foreign and local anti-bribery and health care compliance policies including training on the Company’s own internal compliance program.

MEDEC 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 MEDEC website.

Note: This 2015 MEDEC Code of Conduct supersedes and replaces all previous MEDEC Codes of Conduct. Companies will communicate the principles of this Code to their employees, agents, dealers and distributors with the expectation that they will adhere to this Code. All Companies have an independent obligation to ascertain that their interactions with Healthcare Professionals 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.
Appendix A – Glossary

MEDEC Code of Conduct Glossary

Advertisement  Includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the medical technology

Bona Fide  In good faith, without fraud or deceit

Charitable Donation  The making of a financial or medical technology gift to a registered charitable organization with no expectation of benefit

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  MEDEC Member company / companies

Consultant  A Healthcare Professional who is engaged by a Company under a consulting agreement

Consulting Arrangement  Any relationship in which services are provided to a Company by a Healthcare Professional in exchange for remuneration

Continuing Medical Education (CME)  A specific form of continuing education that helps those in the medical 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  Communicating information directly concerning or associated with the use of Companies’ medical technologies, e.g., information about disease states and the benefits of medical technologies to certain patient populations

Educational Grant  A financial or medical technology contribution made to an organization in exchange for support of an educational activity.

Entertainment  Includes, but is not limited to, dancing or arrangements where live music is the main attraction, sight-seeing trips, theatre excursions, sporting events and other leisure arrangements.

Evaluation Products  Capital or disposable medical technology products provided by Companies at no charge to Healthcare Professionals for a limited amount of time in order for the product to be evaluated for its ability to meet certain functional requirements and its ease of use.

Faculty Member  a Healthcare Professional who is a genuine speaker at a Third Party Educational Conference including as a participant in a panel of speakers

Gift  Something voluntarily transferred by one person to another without compensation

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.
Grant  A financial or medical technology contribution made to an organization in exchange for support of an educational or research activity. Generally includes an expectation that something of value will be received in return for the ability of the Grantor to withhold payment or request a return of funds if the performance does not occur.

Health Care Institution  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 Technologies (other than the Company’s contracted Third Party Intermediaries), the administration of Medical Technology.

Healthcare Professionals (HCP)  Individuals and entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ medical technology products 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.

MEDEC  Canada’s Medical Technology Companies

Medical Technology  Medical products, technologies and related services and therapies use to diagnose, treat, monitor, manage and alleviate health conditions and disabilities

Reasonable  Related to meals, travel, and accommodations, means in accordance with the Company’s corporate travel policies and the policies of the Healthcare Professional’s organization

Research Grant  A financial or medical technology contribution made to an organization in exchange for support of a research activity. A research grant is usually given with the expectation that the data or manuscript will be made available to the Grantor.

Research Institution  Any institution, corporation, government body, agency or committee and any other organization involved in; investigation or experimentation aimed at the discovery and interpretation of facts, revision of accepted theories or laws in light of new facts, or practical application of such new or revised theories or laws whose studies are reviewed and approved by an accredited Ethics Review Board.

Requesting Organization  Organization responsible for soliciting support from Companies. Can include Educational Institutions, Charitable, Research, or Professional Organizations

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

Site Visit  An event during the sales process in which a Healthcare Professional travels to a Company’s location to participate in activities that cannot be provided at the Healthcare Professional’s home location, such as: demonstration of non-portable equipment and observing the manufacturing process.

Special Access  A program run through Health Canada that allows Healthcare Professionals to gain access to medical devices that have not yet been approved for sale in Canada. Special Access is requested in emergency use cases or when conventional therapies have failed, are unavailable or are unsuitable to treat a patient.

Sponsor  A person or organization that pays the cost of an activity or event in return for the right to advertise and promote during the activity or event (Merriam-Webster).

Sponsorship  The right to advertise during an event or activity purchased by a person or organization.

Training  Training on the safe and effective use of medical technologies.
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 policymaking nature and for the genuine purpose of promoting scientific knowledge, medical advancement, or the delivery of effective healthcare.

Third Party Intermediary  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, principal agent, dealer, reseller, distributor, consultant, intermediaries, business partner or any representative acting on behalf of the Company in a sales capacity.

Value Add  Free-of-Charge product or financial payment provided as a part of an executed sales contract. Value Adds must be clearly indicated as such in the contract or tender response. Examples include: medical technology, warranty upgrades, service, training, and/or funding for education, fellowships, or research.
Appendix 8

MEDEC Medical Imaging Site Visit Guidance*

*(includes the following 3 documents: 1) MEDEC Medical Imaging_Staging an Effective Site Visit Guidance Document_March 2016 Update, 2) MEDEC Medical Imaging_Guidance for Effective Product Demonstrations including Checklist_Diagnostic Imaging March 2016 Update, 3) MEDEC Medical Imaging_Guidance for On-Site Product Demonstrations Including Checklist_PACS April 2016)*
GUIDANCE FOR STAGING AN EFFECTIVE SITE VISIT

PURPOSE OF DOCUMENT

This document has been developed by MEDEC to provide guidance to its Membership in responding to site visit requests by prospective purchasers. The objectives of this document are to: i) promote consistent, fair and transparent processes within the vendor community, ii) encourage accountability for public funding and optimal allocation of resources and iii) provide guidelines for effective and efficient Site Visits for all involved parties (ie. vendors, purchasing organizations, and hospitals).

For the purpose of this document, a “purchasing organization” is defined as an organization with an official interest and participation in the decision making process, including hospitals, clinics, purchasing groups, local or regional health boards, etc. A modality is considered to be product areas such as Angiography, CT, MR, Computed Radiography, Digital Radiography, PACS, etc.

MEDEC Members understand the occasional need for prospective purchasers (“purchasing organizations”) to evaluate products at clinical and/or manufacturing sites, as an important part of the equipment selection process. Ensuring quality site visits and an optimal experience is of paramount importance to the MEDEC members as well as to the purchasing organizations. If deemed appropriate by members, they may agree to fund such evaluations and visits in accordance with the following limitations and directions:

1. Site Visit Planning

   In order to allow adequate time to organize site visits and effectively meet the purchasing organization’s objectives, a minimum of (4) four weeks written notice is requested for all site visits. It is also recommended that specific site visit dates be published as part of each tender, and that site visit dates and participants (along with the participants information – contact info, travel documents, etc required for travel if applicable) be confirmed upon publication of “short listed” vendors. This will allow MEDEC members to co-ordinate travel to best accommodate the purchasing organization.

   Site visit plans may be shared by vendors in order to improve efficiency of scheduling for all participants involved but may not be used to increase the recommended number of attendees.
GUIDANCE FOR STAGING AN EFFECTIVE SITE VISIT (cont’d)

2. Site Visit Location

Every effort will be made to conduct site visits locally where local sites best represent the Member’s product of focus for procurement. For multi-modality purchases, the site visit may include one location per single modality.

3. Number of Purchasing Organization Representatives Permitted on Site Visits

Purchasing organization representatives should be employees or team members with clinical privileges at the purchasing organization or relevant hospital. As visits are for the sole purpose of clinical evaluation of products, site visits should only include clinical personnel such as physicians, technologists, administrative directors, physicists and biomedical engineers. For PACS or RIS-related Visits, Clinical IT, IT Admin and/or IT Consultants are encouraged to participate.

It is also recognized that in some instances, a non-clinical representative from the purchasing organization may be required to attend the site visit to ensure fairness and integrity of the process. To respect patient privacy during the site visit, only clinicians can be present in patient treatment areas; all non-clinical attendees are requested to stay outside of rooms where patients are undergoing treatment (e.g. angiography suites).

All of the guests listed above will be included in the total number of Purchasing Organization attendees whose travel and expenses can be covered by the members as outlined below:

a) Single modality projects cannot exceed a total of 3 purchasing organization representatives.
b) Multi-modality projects cannot exceed a total of 5 purchasing organization representatives.
c) Bulk buy/multi-site projects cannot exceed 7 purchasing organization representatives.

Note: Multi-site organizations are considered a single purchasing organization for the same modality regardless of the number of sites represented.

Should the purchasing organization request additional representatives, that is allowable however the purchasing organization will be responsible for paying all associated travel and other expenses for such representatives.

There may be some consideration for the addition of a maximum of one more representative to the above limits if there is a need for multiple sub-specialty representation. The additional representative will represent the combined interests of the multiple sub-specialties and will be mutually agreed upon by all members.
GUIDANCE FOR STAGING AN EFFECTIVE SITE VISIT (cont’d)

4. Number of Visits

Only one (1) visit per single modality project should be made. Members should request that the representatives required for equipment selection be identified at the time of the site visit request and that all travel information be provided to ensure timely booking of any travel arrangements that may be required. To support fairness, the purchasing organizations must utilize their best efforts to ensure that the identified representatives do not change throughout the equipment selection process.

5. Duration of Site Visits

The duration of site visits shall be no longer than is necessary to evaluate the products and their clinical and technical capabilities. MEDEC Members shall provide the purchasing organization with an itinerary prior to the commencement of the site visit that clearly identifies the equipment and model that is being demonstrated.

The MEDEC Code of Conduct applies, and will be followed regarding any activities and interaction on site visits.

6. Screening Policies for Entry into OR Suites or Other Specialty Areas

Any requirements for screening at host sites (i.e. proof of insurance, NDAs, security checks, immunizations…) must be communicated by the Vendor, to the Evaluation Team well in advance of the Site Visit.

7. Travel Expenses and Meals

MEDEC Members will offer the same travel arrangements to Purchasing Organizations as are offered to their own employees. Business Class or First Class travel is not permitted nor is it reimbursable by MEDEC members.

Meals may be provided as an occasional business courtesy when part of a bona fide exchange of scientific, educational or business information. The time, duration of meals, and the venue in which they are provided should always be subordinate to the business purpose, and fall within each Company’s compliance policies. Should the purchasing organization have a more restrictive policy than MEDEC’s, it is the purchasing organization’s policy which will be applied.

This MEDEC Site Visit Guidance shall apply to all site visits whether the customer or vendor is paying for the travel.
GUIDANCE FOR STAGING AN EFFECTIVE SITE VISIT (cont’d)

8. Escalation of Member Issues about a Site Visit

Should any concerns related to Site Visit requests arise amongst MEDEC Members, the member organization will contact MEDEC, who will in turn, address these concerns with the purchasing organization, explaining why/how their request does not fit with MEDEC’s Site Visit Guidance.
Diagnostic Imaging – Updated March 2016

GUIDANCE FOR CONDUCTING AN EFFECTIVE ON-SITE PRODUCT DEMONSTRATION & EVALUATION

This document has been developed by MEDEC in consultation with healthcare organizations to provide guidance to Membership and to prospective purchasers on how to prepare for and conduct effective on-site product demonstrations and evaluations.

The objectives of this document are to: i) promote consistent, fair and transparent processes within the vendor community, ii) encourage accountability for public funding and optimal allocation of resources and iii) ensure that all stakeholders (hospitals, independent healthcare facilities, purchasing organizations, and vendors) maximize the benefits afforded by on-site product demonstrations and evaluations through a consistent understanding of the key requirements.

A “Checklist” has also been included in the Appendix to assist the Demonstration Co-ordinator in preparing for and documenting key elements of a successful demonstration process.

Definition:

On-site product demonstrations & evaluations are situations where healthcare organizations evaluate equipment in their own clinical environment on a short term basis in the presence of the vendor company as part of the equipment selection process. The equipment remains the property of the company over the course of the evaluation. The company in consultation with the healthcare facility shall determine if providing an on-site demonstration/evaluation is appropriate in each circumstance.

For equipment where the care, custody and control does not remain with the vendor, policies and documentation related to “loaning equipment” will apply.

Stage One: Pre-Demonstration & Evaluation Requirements

1. Notice of Demonstration

Upon short list notification and a request to provide product demonstrations, MEDEC members will use best efforts to arrange such demonstrations as soon as they are able. Based on the availability of the appropriate equipment and resources, this planning and co-ordination could take up to 4 weeks.

In the event that the demonstration or evaluation needs to be cancelled by either party, a minimum of 5 business days written notice will be provided.
GUIDANCE FOR CONDUCTING AN EFFECTIVE ON-SITE PRODUCT
DEMONSTRATION & EVALUATION (cont’d)

2. Demonstration & Evaluation Agreement

Any required Demonstration Agreement should be communicated well in advance of the demonstration date and signed by both parties prior to commencement of the demonstration.

3. Key Information and Requirements prior to Demonstration & Evaluation

In order to optimize the demonstration, the following information should be shared and agreed to by all parties prior to the demonstration or evaluation:

- Identify and book accordingly the types of procedures that wish to be evaluated so that the demonstration equipment can be appropriately configured
- Where appropriate, consider reducing the number of patient bookings during the demonstration period to allow for a better evaluation by staff
- Identify evaluation criteria, key stakeholders & clinical specialties to participate in demo
- Each organization (hospital & vendor) to identify a key contact to facilitate communications between the parties (name, title, phone number & email address)
- Mutually agree to the dates of the demonstration, allowing sufficient time for equipment set up and testing prior to clinical demonstrations, time for staff training, days for the demonstration and time for equipment to be packed up and removed from the facility. Times required may vary based on the type of equipment being evaluated.
- Site to communicate to vendor any requirements for screening for entry into OR Suites or Specialty areas (ie. proof of insurance, NDAs, security checks, immunizations…) in advance of the demonstration
- Site to provide appropriate room/space for set-up & testing of demonstration equipment (a lead lined room is required for c-arms and mobile x-ray machines) as well as a secure location should the equipment be required to stay at the site outside of the demonstration hours
- Site to identify a key contact person for networking information and set up and to provide required networking information, such as: IP Addresses, IP Subnet, IP Gateway, DICOM Modality Worklist information & other information as requested by vendor
- Shipping & Receiving: Site to provide the correct “Ship To” address, identify the type of dock available and the opening & closing hours of the Shipping/Receiving Department
- Site to provide a no-charge Purchase Order for the demonstration equipment unless mutually agreed that this is not required
GUIDANCE FOR CONDUCTING AN EFFECTIVE ON-SITE PRODUCT DEMONSTRATION (cont’d)

- Vendor guarantees that all medical devices provided for demonstration have been properly licensed by Health Canada, and that the product being demonstrated fits the exact specifications of that quoted by the vendor.
- With the co-operation of the healthcare facility, vendor is responsible for the delivery, installation and removal of the equipment.

4. Duration of Product Demonstrations & Evaluations

The following are suggested guidelines for the duration of the demonstration and evaluation period, depending on the type of equipment:

- Ultrasound: 3 days maximum
- C-arms, Mobile Radiography: 1 week maximum

Each demonstration will identify in advance a mutually agreed upon delivery date, installation/set up period, training period and a removal date.

Note: For mobile radiography, the first day (typically a Monday) will be used for product delivery, set up & staff training with clinical demonstrations to begin on day two.

5. Escalation of Member Issues about an On-Site Product Demonstration

Should any concerns related to On-Site Product Demonstration requests arise amongst MEDEC Members, the member organization will contact MEDEC, who will in turn, address these concerns with the purchasing organization, explaining why/how their request does not fit with MEDEC’s on-Site Product Demonstration Guidance.
## Appendix: Diagnostic Imaging On-Site Product Demonstration & Evaluation Checklist

<table>
<thead>
<tr>
<th>Stage One: Pre-Demonstration</th>
<th>Most Responsible Person</th>
<th>Date</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Written notice of Dates available to Vendor</td>
<td>Manager</td>
<td>Up to 4 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Return Signed Demo Agreement to Vendor (if required)</td>
<td>Stakeholders</td>
<td>Up to 4 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Communicate to vendor any requirements for screening for entry into OR Suites or Specialty areas</td>
<td>Manager</td>
<td>Up to 4 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Provide no charge PO for shipping and tracking the demo equipment</td>
<td>Purchasing</td>
<td>Up to 4 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Provide complete shipping and delivery instruction</td>
<td>Manager</td>
<td>Up to 4 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Identify the type of dock and Hours that is available at the Shipping/Receiving Department - notify Vendor</td>
<td>Purchasing</td>
<td>Up to 4 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Identify key stakeholders that will be participating / evaluating during the product demonstration - communicate to Vendor &amp; staff</td>
<td>Stakeholders</td>
<td>Up to 4 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Book down the regular patient work load on the system being evaluated</td>
<td>Manager</td>
<td>Up to 4 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Provide Vendor with evaluation schedule - start times, rooms etc.</td>
<td>Senior or Charge Tech</td>
<td>Up to 2 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Book room for testing &amp; setup of demo equipment (a lead lined room is required for c-arms &amp; mobile x-ray machine setup), and confirm a secure location for the equipment if required to remain on-site outside of demonstration hours</td>
<td>Manager</td>
<td>Up to 2 weeks prior</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stage Two: Clinical Demonstration &amp; Evaluation Day</th>
<th>Most Responsible Person</th>
<th>Date</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vendor rep(s) to register/sign-in according to facility policy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vendor rep(s) to observe facility policy pertaining to infection control</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confirm Bookings reduced to accommodate Demo</td>
<td>Senior or Charge Tech</td>
<td>Day before start</td>
<td></td>
</tr>
<tr>
<td>Move system from biomed to final evaluation room</td>
<td>BIOMED / Vendor</td>
<td>Day before start</td>
<td></td>
</tr>
<tr>
<td>Allow vendor access to system 1 hour prior to start time</td>
<td>Senior or Charge Tech</td>
<td></td>
<td></td>
</tr>
<tr>
<td>One Hour system training and overview prior to first case</td>
<td>Stakeholders / Vendor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At the end of each day or as pre-determined by the customer and vendor, review to ensure required cases have been completed</td>
<td>Stakeholders / Vendor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At end of the demo, the customer ensures (with support of the vendor) that all patient data is removed and the equipment is cleaned according to vendor provided recommendations</td>
<td>Senior or Charge Tech / Vendor</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
GUIDANCE FOR CONDUCTING AN EFFECTIVE ON-SITE PRODUCT DEMONSTRATION & EVALUATION

This document has been developed by MEDEC in consultation with healthcare organizations to provide guidance to Membership and to prospective purchasers on how to prepare for and conduct effective on-site product demonstrations and evaluations.

The objectives of this document are to: i) promote consistent, fair and transparent processes within the vendor community, ii) encourage accountability for public funding and optimal allocation of resources and iii) ensure that all stakeholders (hospitals, independent healthcare facilities, purchasing organizations, and vendors) maximize the benefits afforded by on-site product demonstrations and evaluations through a consistent understanding of the key requirements.

A “Checklist” has also been included in the Appendix to assist the Demonstration Co-ordinator in preparing for and documenting key elements of a successful demonstration process.

Definition:

On-site product demonstrations & evaluations are situations where healthcare organizations evaluate equipment in their own clinical environment on a short term basis in the presence of the vendor company as part of the equipment selection process. The equipment remains the property of the company over the course of the evaluation. The company in consultation with the healthcare facility shall determine if providing an on-site demonstration/evaluation is appropriate in each circumstance.

For equipment where the care, custody and control does not remain with the vendor, policies and documentation related to “loaning equipment” will apply.

Stage One: Pre-Demonstration & Evaluation Requirements

1. Notice of Demonstration

Upon short list notification and a request to provide product demonstrations, MEDEC members will use best efforts to arrange such demonstrations as soon as they are able. Based on the availability of the appropriate equipment and resources, this planning and co-ordination could take up to 4-6 weeks.

In the event that the demonstration or evaluation needs to be cancelled by either party, a minimum of 5 business days written notice will be provided.
GUIDANCE FOR CONDUCTING AN EFFECTIVE ON-SITE PRODUCT DEMONSTRATION & EVALUATION (cont’d)

2. Demonstration & Evaluation Agreement

Any required Demonstration Agreement should be communicated well in advance of the demonstration date and signed by both parties prior to commencement of the demonstration.

3. Key Information and Requirements prior to Demonstration & Evaluation

In order to optimize the demonstration, the following information should be shared and agreed to by all parties prior to the demonstration or evaluation:

- Where appropriate, confirm that staffing levels are adequate in order to allow sufficient time for appropriate staff to attend the demonstration and evaluate the equipment
- Agree itinerary that clearly identifies what will be presented during the demonstration and the types of procedures to be evaluated
- Identify evaluation criteria, key stakeholders & clinical specialties to participate in demo
- Each organization (hospital & vendor) to identify a key contact to facilitate communications between the parties (name, title, phone number & email address)
- Mutually agree to the dates of the demonstration, allowing sufficient time for equipment set up and testing prior to clinical demonstrations, time for staff training, days for the demonstration and time for equipment to be packed up and removed from the facility. Times required may vary based on the type of equipment being evaluated.
- Site to provide appropriate room/space for set-up and testing of demonstration equipment including tables, access to power and internet
- Site to identify a key contact person for networking information and set up and to provide required networking information. Demonstration should be “stand-alone” and only require internet access
- Shipping & Receiving: Site to provide the correct “Ship To” address, identify the type of dock available and the opening & closing hours of the Shipping/Receiving Department
- Site to provide a no-charge Purchase Order for the demonstration equipment unless mutually agreed that this is not required
- Vendor guarantees that all medical devices provided for demonstration have been properly licensed by Health Canada, and that the product being demonstrated fits the exact specifications of that quoted by the vendor. If not restricted or defined as inappropriate through a competitive process, if a “future technology” is demonstrated, it will be clearly labeled as “Product Not Licensed For Sale in Canada”
- With the co-operation of the healthcare facility, vendor is responsible for the delivery, installation and removal of the equipment
GUIDANCE FOR CONDUCTING AN EFFECTIVE ON-SITE PRODUCT DEMONSTRATION (cont'd)

4. Duration of Product Demonstrations & Evaluations

The following is a suggested guideline for the duration of the demonstration and evaluation period, depending on the type of equipment:

   Day 1:  Equipment Delivery and Installation

   Days 2-4:  Product Demonstration (timing will be determined based on size of organization)

Each demonstration will identify in advance a mutually agreed upon delivery date, installation/set up period, training period and a removal date.

Stage Two: Requirements during the Demonstration & Evaluation Period

- Confirm that staffing levels are adequate to allow staff sufficient time to attend and effectively evaluate the demonstration

- Confirm arrangements for shipping materials/crates – to be stored in a secure area on site or to remain with vendor carrier and returned when equipment is removed from site

- Where applicable, vendor representatives shall register / sign-in according to the healthcare facility policies & procedures

- Vendor representative to unpack, set up and test equipment in pre-designated area and if required work with assigned hospital personnel to connect to the hospital internet

- Demonstration equipment remains the property of the vendor, therefore the equipment must be used as instructed by the vendor during the training session and may not be relocated, modified or connected to any other equipment without prior consent of vendor

- At the end of each day, customer and vendor will review the effectiveness of the demonstration, and make any appropriate adjustments to the equipment and/or protocol to ensure that the objectives of the product evaluation are being met

- Site will be responsible for ensuring that the demonstration equipment is safely and securely stored when not in use.

5. Escalation of Member Issues about an On-Site Product Demonstration

Should any concerns related to On-Site Product Demonstration requests arise amongst MEDEC Members, the member organization will contact MEDEC, who will in turn, address these concerns with the purchasing organization, explaining why/how their request does not fit with MEDEC’s on-Site Product Demonstration Guidance.
### Appendix: Picture Archiving Communications Systems On-Site Product Demonstration & Evaluation Checklist

#### Stage One: Pre-Demonstration

<table>
<thead>
<tr>
<th>Task</th>
<th>Lead(s)</th>
<th>Date</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Written notice of Dates available to Vendor</td>
<td>Manager</td>
<td>Up to 4-6 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Return Signed Demo Agreement to Vendor (if required)</td>
<td>Stakeholders</td>
<td>Up to 4 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Ensure appropriate staffing levels to provide time for appropriate staff to attend demonstration and evaluate PACS solution</td>
<td>Manager</td>
<td>Up to 4 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Agree itinerary that identifies what will be presented during demonstration</td>
<td>Stakeholders</td>
<td>Up to 4 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Provide no charge PO for shipping and tracking the demo equipment if equipment is being delivered to site</td>
<td>Purchasing</td>
<td>Up to 4 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Provide complete shipping and delivery instruction (if required)</td>
<td>Manager</td>
<td>Up to 4 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Identify the type of dock and Hours available at the Shipping/Receiving Department - notify Vendor (if required)</td>
<td>Purchasing</td>
<td>Up to 4 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Identify key stakeholders that will be participating / evaluating during the product demonstration - communicate to Vendor &amp; Staff</td>
<td>Stakeholders</td>
<td>Up to 4 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Provide Vendor with evaluation schedule - start times, rooms etc…</td>
<td>Senior or Charge Tech</td>
<td>Up to 2 weeks prior</td>
<td></td>
</tr>
<tr>
<td>Book room for testing &amp; setup of demo, and confirm a secure location for the equipment if required to remain on-site outside of demonstration hours</td>
<td>Manager</td>
<td>Up to 2 weeks prior</td>
<td></td>
</tr>
</tbody>
</table>

#### Stage Two: Clinical Demonstration & Evaluation Day

<table>
<thead>
<tr>
<th>Task</th>
<th>Lead(s)</th>
<th>Date</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confirm staffing levels to accommodate Demo</td>
<td>Manager</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vendor rep(s) to register/sign-in according to facility policy &amp; procedures</td>
<td>Senior or Charge Tech/Vendor</td>
<td>Day before start</td>
<td></td>
</tr>
<tr>
<td>Vendor Rep(s) to unpack, set up &amp; test equipment in designated area and link to internet (if required)</td>
<td>Senior or Charge Tech/Vendor</td>
<td>Day before start</td>
<td></td>
</tr>
<tr>
<td>Evaluate effectiveness of demonstration against product evaluation objectives</td>
<td>Stakeholders/Vendor</td>
<td>End of each day</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 9

Has the Pendulum Swung too far? The Impact of Group Purchasing Organizations (GPOs) and Shared Services Organizations (SSOs) on Small and Medium Enterprises (SMEs) in the Medical Device Industry – Rick Audus
Has the Pendulum Swung too far?
The Impact of Group Purchasing Organizations (GPOs) and
Shared Services Organizations (SSOs) on Small and
Medium Enterprises (SMEs) in the Medical Device Industry

By

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Memorial University of Newfoundland

and

Miranda V Polgar
Faculty of Medicine
Memorial University of Newfoundland

March 2012

¹ This paper was researched and written under contract to the Life Science Industries Branch of Industry Canada, but represents the findings and views of the author. Any errors or omissions are our responsibility alone.
1. Executive Summary

Canadian hospitals and health authorities are increasingly purchasing medical devices through shared services organizations (SSOs) and group purchasing organizations (GPOs). By combining purchasing volume, this is thought to give increased market power to the purchaser, allowing them to achieve lower prices. A number of provinces have set up SSOs to coordinate tenders and two national GPOs (MedBuy and HealthPro) have emerged.

Theoretical and anecdotal evidence suggests that lower costs should be achieved in the short-run, particularly for standard or commodity type items. However, it is less clear that cost savings will be achieved in the high-tech segment, nor is it clear what the long-term implications of an increasingly concentrated medical device industry will be. Of particular concern is that by creating barriers to Canadian small and medium size enterprises (SMEs), a potentially important economic contributor and innovation driver will not reach its potential.

To examine these issues in more detail, we conducted a series of interviews with representatives from Canadian SMEs in the medical device industry as well as a number of other key stakeholders. A number of themes surrounding the tendering process emerged:

- It is not conducive for the uptake of disruptive technologies that have the potential to change the way patients interact with the health care system.
- It tends to favour larger, often multi-national firms that can supply hospitals across Canada. This procurement process is problematic for Canadian SMEs that are unable to compete on such a large scale.
- It is unnecessarily bureaucratic and cumbersome.
- Contracts tend to be too long in duration and often bundle together products, favouring firms with broader product lines.
- It restricts access to end-users, potentially stifling innovation.
- There is a lack of strategic purpose in purchasing and in particular, there is no advantage to being a Canadian firm.
- It may be advantageous to split the medical device sector into low and high technology segments. The GPO/SSO procurement model may be advantageous in the low-tech segment, but should be avoided in the high-tech segment.
Following these consultations and a review of the literature, we make the following recommendations:

1. Ring-fenced funding needs to be dedicated to the purchase of innovative medical technologies.

2. Firms and clinicians need to connect and form partnerships with hospitals and health authorities to develop and implement potentially disruptive technologies. A funding program should be provided to give grants to promising partnerships.

3. Tendering should be simplified as much as possible to encourage wider participation.

4. As much as existing trade agreements will allow, every possible advantage in the tendering process should be conferred to Canadian firms.

This is an industry of potential strategic importance to the Canadian economy as well as one that can improve the lives of people around the world through the development of new and innovative technologies. With financial support and some changes in the tendering process, this can be achieved.
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A. Access

B. Complexity

C. Rigidity

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GPOs and SSOs are a Barrier to Entry

The RFP Process is too Rigid and Bureaucratic
Introduction

In a recent report examining Ontario's public finances, (Ministry of Finance, 2012) Drummond, et al. shone a light on a fiscal crisis emerging in health care. An aging population and further advances in technology are driving health care costs higher than the rate of economic growth – a situation that is not sustainable. While the focus of this report was aimed at Ontario, every other Canadian province faces the same health care expenditure bubble.

While examining strategies to cope with an aging demographic (such as increasing fertility rates or encouraging more immigration) are beyond the scope of this paper, we can examine how we utilize health technology. Specifically, the focus herein is how this cost pressure has influenced medical device procurement and also how we can potentially make better use of technological advances through procurement to reduce the reliance on the health care system.

One of the strategies adopted by Ministries of Health and Regional Health Authorities (RHAs) to manage the cost of medical devices is to group together to collectively organize purchases of medical devices. Some provinces have formed Shared Service Organizations (SSOs) that - in addition to coordinating medical device purchases - seek to achieve economies of scale in other administrative functions. In addition, many RHAs have joined a Group Purchasing Organization (GPO), which seeks to lower costs by joining forces to tender for medical devices. Members of GPOs (and in Canada there are two dominant GPOs: MedBuy and HealthPRO) indicate that they are interested in participating in a particular Request for Proposals (RFP), and they then commit to the term negotiated with the vendor selected by the RFP.

Earlier research by Audas (2012) suggested that the movement towards concentrated and centralized purchasing of medical devices may be adversely affecting Canadian small and medium sized enterprises (SMEs) in this sector. The aim of this paper is to examine the impact of GPOs and SSOs on these firms and subsequently to explore the broader implications for developing and adopting innovative technologies.

This movement towards centralized purchasing raises a number of important issues. Do GPOs and SSOs act as a barrier to entry to SMEs in the medical device industry? In the attempt to professionalize and address accountability issues in the purchasing function, have the bureaucratic and administrative requirements made the purchase of medical devices unnecessarily rigid and constrained? By increasing the burden of tendering and making the prospect of getting innovative technologies into the market more difficult, is Canada lagging behind other countries in terms of fostering innovation? Is an industry that could be a larger contributor to exports and in the employment of highly skilled individuals failing to reach its full potential?
The focus of this paper is to examine procurement policies in Canada – specifically in Ontario and Quebec – to examine the extent to which the increased reliance on GPOs and SSOs has resulted in greater challenges for the SMEs to be active participants in markets, and to explore the extent to which this may be an impediment to innovation.

There are three broad themes that are addressed in this report:

The first theme is that the GPO/SSO procurement model – while perhaps delivering lower short-run costs to their members – disadvantages SMEs in the medical device sector.

The second is that innovative and potentially disruptive medical technology – for instance the trend towards personalized medicine – has the potential to change the way patients utilize and interface with the health care system and as such may result in much more efficient health care delivery. However the GPO/SSO procurement model is an impediment to the uptake of novel technology.

The third theme is that the medical device industry has the potential to play a much more prominent role in the Canadian economy. However, to achieve this potential, it will require support and more strategic direction. It will also require a greater openness towards innovation from Group Purchasing Organizations (GPOs) and Shared Service Organizations (SSOs).

The paper is organized as follows: Section 2 provides an overview of the medical device industry in Canada highlighting key trends. Section 3 examines procurement practices in Ontario and Quebec. Section 4 provides a summary of a series of interviews conducted with representatives from SMEs in the medical device sector. An important theme that emerged from this is that the GPO/SSO model of procurement makes innovation more difficult and hinders SMEs in this sector. This section also includes summaries of discussions with GPOs and SSOs that we have conducted as well as five organizations across Canada that seek to advance medical device firms with innovative medical technologies. Section 5 examines this in light of models of innovation and evaluates the impact that GPOs and SSOs have on innovation in the medical device sector. Section 6 provides a discussion of the key findings and indicates possible policy options. Section 7 concludes.

2. The Medical Device Industry in Canada

The medical device segment of the health care market is a multi-billion dollar industry in Canada, producing and selling everything from well-established disposable commodities to leading edge new technologies that have the potential to save lives and change how medicine is practiced. There is a focus on enhancing product lines and innovation. Firms that successfully innovate can find new markets anywhere in the globe.
According to Industry Canada, Small and Medium Enterprises (SMEs) can be defined as having annual revenue between $30,000 and $5,000,000 and having less than 100 employees. An enterprise can be defined as the organizational unit of a business that directs and controls the allocation of resources relating to its domestic operations, and for which consolidated financial and balance sheet accounts are maintained from which international transactions, an international investment position and a consolidated financial position for the unit can be derived (Industry Canada, 2012b).

A firm with a novel technology that offers substantial potential health gains can often extract a significant price for that product. Indeed, selling prices far above the marginal cost to produce are justified on the grounds that large margins are needed to fund future research and development (R&D) to develop even more new products or to further enhance existing products.

When firms hold patents on particular products this potentially conveys a great deal of market power to the supplier. As such, health authorities tend to be forced to pay up to their maximum willingness-to-pay for that particular device. Furthermore earlier research into price transparency in medical devices concluded that a lack of price transparency in this sector might not be driven by firms, but rather by GPOs. Further analysis suggested that GPOs survival depends non-disclosure of prices (Audas, 2012).

As of 2005, there were 1101 medical device facilities recorded with a total of 998 firms. Small facilities are defined as fewer than 49 employees, which comprised 94% of the medical device industry in 2005. Medium and large facilities each make up 6% of this industry. 90% of medical device industry is Canadian owned. Employment levels rose from 22,000 to 26,000 from 2000-2005. In 2008, the size of the Canadian medical devices market was valued at $6.4 billion. The United States is the primary market for Canadian medical devices exports, accounting for some 71% in 2009. (Industry Canada, 2012a)

3. Procurement Directives and Practices: Trends and Implications

In this section we examine the broad procurement trends in Canada, with a particular view to examining the move towards consolidating purchases through GPOs and SSOs. As noted earlier, increasing cost pressure has resulted in RHAs and Ministries of Health seeking ways to better manage procurement to extract lower prices from vendors. This has resulted in a proliferation of umbrella organizations to seek economies of scale in administrative functions and to gain more market power by concentrating purchasing. For RHAs, this allows them to get more competitively priced medical devices and reduces the administrative burden of managing numerous purchasing contracts simultaneously.
However, an argument can be made that GPOs and SSOs are symptomatic of a culture of cost containment and may adversely impact the drive towards continual improvement and the uptake of disruptive technologies. So even if the GPO/SSO procurement model were abandoned, it would not alleviate the need to keep prices low and short-run cost pressures would still make it difficult for purchasers to adopt novel technologies, even if they have the potential to be cost saving in the longer-term.

**Role of Physician Preference Items**

Historically, individual specialist physicians wielded considerable influence on the purchasing decisions made by hospitals and health authorities. In some cases physicians may have had a financial stake in a medical device firm and they would use their influence to get their preferred products purchased by their local health authority. If products were successfully implemented, then this would create opportunities for firms to expand to new markets with a strong body of evidence supporting their product’s efficacy.

There seems to be a consensus view in the literature that these Physician Preference Items (PPIs) have caused significant problems for hospital administrators and health authorities (e.g. Lerner, et al. 2008). The over-arching concern was a conflict of interest between the individual physician who is promoting a particular product and the need for RHAs to ensure procurement decisions were made with value-for-money as the key decision criterion.

The GPO/SSO procurement model largely eliminates the influence of individual physicians on procurement decisions. Undoubtedly, this has increased the level of standardization, transparency and accountability in medical device procurement. However, it may have also led to eliminating a natural way through which SMEs with innovative products could gain entry into markets.

As such there is an apparent tension between the short-run cost pressures facing the health care system and the SMEs who are attempting to find markets for innovative and potentially disruptive technologies. Addressing short run cost pressures through the use of GPOs and SSOs may come at the cost of foregoing novel technologies that could be developed and improve health outcomes for Canadians and represent an important engine for economic growth for Canadian industry and the subsequent high quality jobs that would follow.

Historically governments have used the allocation of public dollars with a dual purpose. First, governments engaged in procurement to provide essential public services. Second, this procurement may be targeted to support industries that might have strategic value in terms of growing a market for export and identifying areas where domestic firms have the potential to be among world leaders. Allocation of public funds needs to balance the short-run cost pressures currently facing the
Canadian health care system, but must also recognize that the medical device industry is of strategic importance to Canada and that strategic purchasing decisions can provide necessary support to an important Canadian industry.

In the sections below we examine procurement practices in Ontario and Quebec in more detail.

**Procurement Practices in Ontario**

The Broader Public Sector (BPS) Accountability Act (2010), was introduced into Ontario in order to ensure goods and services are acquired through a fair, open and transparent process; to set stringent guidelines for BPS organizations to follow; and to ensure there is consistency among the way BPS organizations manage themselves. The directive follows five key principles: accountability, transparency, value-for-money, quality service delivery and process standardization. As per the BPS procurement directive, these five principles are highlighted below:

**A. Accountability**
- Organizations must be accountable for the results of their procurement decisions and the appropriateness of the processes.

**B. Transparency**
- Organizations must be transparent to all stakeholders. Wherever possible, stakeholders must have equal access to information on procurement opportunities, processes and results.

**C. Value for Money**
- Organizations must maximize the value they receive from the use of public funds. A value-for-money approach aims to deliver goods and services at the optimum total lifecycle cost.

**D. Quality Service Delivery**
- Front-line services provided by organizations, such as teaching and patient care, must receive the right product, at the right time, in the right place.

**E. Process Standardization**
- Standardized processes remove inefficiencies and create a level playing field.

The BPS regulates a supply chain code of ethics, which does not displace an organization’s code of ethics, but merely becomes an addition to it. This ethics code surrounds three key ethical traits: personal integrity and professionalism,
accountability and transparency, and compliance and continual improvement. As per the Broader Public Sector procurement directive, these three ethical principles are highlighted below:

F. Personal integrity and professionalism
   o Individuals involved must uphold integrity by being honest, caring, due diligence and show respect for one another.
   o All conflicts of interested must be avoided in this process, i.e. accepting a gift, giving preferential treatment to a vendor, etc.

G. Accountability and transparency
   o Contract and purchasing must be fair, transparent and conducted with a view to obtaining the best value for public money.

H. Compliance and continuous improvement
   o The code of ethics mandated by the organization and the laws of Canada and Ontario must be abided by at all times.
   o Continuous improvement on supply chain policies and procedures is required.

The Canadian medical technology industry’s national association is MEDEC. As per MEDEC’s website, they are the primary source for advocacy, information, and education on the medical technology industry for members, the greater healthcare community, industry partners, and the general public. MEDEC ultimately wants to achieve advancement of health outcomes for patients in Canada using proven and safe technology developed by their members. MEDEC has outlined five key priorities in response to Ontario’s BPS procurement directive:

1. Adoption of new medical device technology
   o Need a direct link between the needs of the health system and innovative technologies
   o Need to manage new technology appropriately

2. Development of medical device technology
   o Need a development process supported by the Ontario Health Technology Advisory Committee, industry, research and healthcare professionals

3. Improvement of the procurement process and access to market
   o Need to help clarify the new procurement process by:
     ▪ Developing a handbook “how-to”
     ▪ Bid process takes into consideration the value of innovative technology
     ▪ Follow a collaborative approach in developing standardized competitive bid templates
4. **Engagement of the global medical device industry in the Ontario health technology strategy**
   - Use MEDEC to engage the global medical device industry

5. **Sustained advancement of medical device innovation and cost containment**
   - Government to develop a cross ministry “open for business” forum that includes MEDEC

(Ministry of Economic Development and Finance, 2010; MEDEC, 2012)

**Procurement Practices in Quebec**

In Quebec, Bill 100 (An Act to implement certain provisions of the Budget Speech of 30 March 2010, reduce the debt and return to a balanced budget in 2013-2014) was passed in June 2010 to reduce administrative costs within the health sector by 10%. The aim of this legislation was to try to achieve greater economies of scale through increased coordination of purchasing and administrative activities.

Procurement of medical devices in Quebec has been coordinated through 11 SSOs that serve regional amalgamations of health authorities (see www.cpaqsante.qc.ca). However, they are currently in the process of being streamlined to three SSOs, with the view that with greater economies of scale, there will be increased participation in group purchasing that is expected to result in greater cost savings. AQESSS (the Quebec equivalent of the Ontario Hospitals Association) supports the need to reduce costs in the health care system, but believes that participation in group purchasing should be voluntary, rather than compulsory.

Bill 16 (An Act to amend various legislative provisions for health and social services in particular, in order to tighten the process of certification of residences for the elderly) was passed in Quebec in May 2011. This Bill contains legislation that dictates that SSOs will manage calls for tenders and contracts for the procurement of medical supplies and devices. They will also assist with helping agencies define their supply and device needs and will eventually take on the role of regional distribution of supplies and devices. The three SSOs will develop areas of expertise and will coordinate province-wide tenders in their respective areas of expertise.

There is a long history in Quebec of hospitals collaborating on purchasing, with the largest of the 11 existing SSOs (SigmaSante for the Greater Montreal area) having been formed in 1994 and with an umbrella organization called AQLASS

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2 A good example of this kind of practical collaboration between industry and government is the EXCITE initiative which is the result of a consultative process undertaken by Ontario. See: https://www.htx.ca/Announcement/call_for_innovative_medical_technologies.htm
(www.aqlass.org) providing support and training to Quebec health authorities since 1970.

No Health Authorities in Quebec are members of the national GPOs (MedBuy and Health Pro).

A list of GPOs and SSOs operating in Ontario and Quebec is provided in Appendix B

4. Interviews with SMEs

Following consultations with Industry Canada and MEDEC, a series of questions were developed and telephone interviews were conducted with representatives from nine firms that would be classified as SMEs in the medical device industry, five advocacy organizations, two SSOs and one GPO. To preserve anonymity quotes are not attributed to individual respondents (unless agreed).

The discussion largely revolved around four main themes.

The first was the view that that there was little support or advantage for being a Canadian firm, employing Canadians and paying Canadian taxes.

The second was that the process of responding to RFPs is very burdensome, complex and rigid and that there was little feedback provided when bids were not successful.

The third theme was that the RFP process was not conducive for the uptake of disruptive technologies.

The fourth theme was that access to end-users impeded product development and innovation. The RFP process does not provide entrepreneurs a satisfactory way to demonstrate their products.

To provide as much insight as possible, the comments of respondents to each of the questions are provided under key themes that emerged in each section.

Interviews were conducted by phone in February and March 2012. Both authors were present for all interviews and key points were transcribed. We detail responses provided to eight questions. In an attempt to maximize the useful data available, all relevant points raised are summarized or directly quoted. Within each question emergent themes are identified.
1) Approximately what proportion of your firm’s Canadian business (in terms of total sales volume) is conducted through tenders run by Group Purchasing Organizations (GPOs) such as HealthPro or MedBuy, or Shared Service Organizations (SSOs)?

The proportion of association with GPOs amongst the interviewed suppliers ranged from 0%-90%. At the lower end of the spectrum, there is a split amongst those vendors engaging with GPOs, but having limited success and those vendors who believe that GPOs are significant obstacle to doing business. This difference can be observed due to the company’s marketing strategy and their association with end users and manufacturers. The consensus was that GPOs and SSOs are capturing a growing proportion of the medical device procurement transactions in Canada.

Some companies distribute only to original equipment manufacturers to avoid the administrative costs resulting from completing RFPs, while other companies are actively trying to engage GPOs in the integration process although to date been unsuccessful (as will be elaborated upon later in this paper). Those who would like to have greater involvement with GPOs are having a difficult time becoming associated with the GPOs. Those who are heavily involved with GPOs state this relationship is increasing due to the increasing share of total medical device purchases that are being coordinated through GPOs. It appears that the companies interviewed have a wide range of experience with GPOs and have a variety of reasons for their particular level of affiliation.

2) Do you see any particular advantages or disadvantages in responding to RFPs through GPOs or SSOs?

This question dominated the discussion with all respondents engaging in a lengthy conversation on this topic. The primary advantage of the GPO/SSO model was identified as potentially being able to offer lower costs to health authorities for commodity-type medical devices. These are areas where there are limited technological advancements and even substantial improvements would be unlikely to significantly appreciate value-for-money. Some respondents believed that once firms became established with GPOs and SSOs, it could result in a secure and predictable revenue stream for multiple years. However this must be tempered with the complement of this point. Firms on the outside of GPOs and SSOs struggle to survive.

The discussion on disadvantages with the GPO/SSO approach was considerably longer, and it was clear that none of the respondents – even those that conducted a considerable amount of business with GPOs and SSOs – considered this to be a positive trend for their business. A significant concern was that this process eliminated their capacity to effectively market and showcase their products and
demonstrate their innovative capabilities. A number of themes emerged in the discussion of the disadvantages of the GPO/SSO procurement model.

**A. Win big, lose big and insider/outsider problem**

A few vendors expressed a problem gaining a relationship with GPOs, and they have focused their main priorities on creating awareness and a rapport with GPOs in order to better sell their products. One vendor stated that when they went to sell their products to direct end users, they got responses such as, “We are a MedBuy Hospital” or “We are a Healthpro Hospital and we cannot see other vendors”.

The vendors expressed frustration in trying to integrate themselves into hospitals because even though they provided sound, logical, money-saving opportunities, the end users are still unable to remove their association with these GPOs.

One vendor stated, “GPOs and SSOs feel that their role is a gatekeeper”. This issue was raised by many of the vendors that were interviewed. Vendors currently associated with GPOs suggested that if they were on a GPO list and have completed an RFP, it is easier to integrate the company’s product into hospitals. One vendor stated, “Once you’re known, there is a high probability of getting repeat business revenue that you can count on.”

A successful bidder is contracted for multiple years, typically between three to five years, and this also contributes to the barrier of entering into the marketplace. Vendors suggested shortening the contract lengths in order to accommodate the rapid turnover of innovative technology and to enable other SME to participate in the bidding process.

Vendors appear to be significantly disadvantaged if they are considered “outsiders” to this procurement process, and many SMEs have been forced to close their business as a result of not being able to integrate themselves with GPOs and then, in turn effectively not being able to integrate themselves into the marketplace.

**B. Administrative burden**

A vendor stated, “If you want to play, you’ve got to pay”. By this he meant that the RFP process requires a considerable amount of effort and resource allocation.

Virtually all vendors discussed the issue around the administrative burden resulting from the RFP process. Effectively, the RFP process becomes a barrier to accessing the marketplace. SMEs may not have the human resources to allocate towards the RFP process, and consequently, this will lead to decreased revenue and possible failure of their business.
One vendor suggested that to respond to an RFP required dedicating two people for 10 days to complete the necessary documentation. To a small organization, this is a sizeable allocation of resources for what might be a low chance of success. A few vendors discussed the need to consider the risk/reward ratio when competing in a business while approaching a new market place, sometimes opting to not respond to RFPs if they perceived the effort to submit a bid as extensive, and the probability of success to be low.

An interesting point that was raised is that while the RFP process is extremely burdensome and is meant to maintain a fair, transparent process in order to achieve the best vendor, organizations may not in fact obtain the best vendor because of the criteria they have set out and the weighting that they have allotted to it. “Purchasers of innovative technology may not be fully equipped to prepare the RFP to cater to them appropriately”, a GPO stated. It was clear from all of the vendors interviewed that the ability to cope with the administrative burden determines how successful a vendor’s bid will be.

One vendor summed this up by saying: “They may have a great piece of technology, but they don’t have the horsepower to get it in.”

C. No conferred advantage for Canadian companies

A few vendors had mentioned that there are no advantages for innovative Canadian companies. According to a vendor, in the past, the province of Ontario would provide a 10% reduction in their tenders if the company was Canadian; however, that incentive has been removed. Another concern was that organizations were accepting bids from outside of Canada, and while they may be initially cheaper, the organization is not contributing to the Canadian economy and building new jobs for Canadians.

D. Government communication issues

Vendors expressed concern regarding the BPS process, GPOs, and SSOs, and that these vendors were unable to maintain communication with governments. The vendors wanted to provide feedback to the government on the process, however they felt that they were chasing government representatives. If they were successful in communicating with these people, their rate of turnover made it impossible to maintain on-going dialogue regarding improving the procurement process in Ontario.

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3 We interpreted this as meaning that a foreign bid of $10 would be treated as being the same price as a Canadian bid of $11.
**E. Lack of innovation / Rigid RFP Process**

The rigid RFP process was discussed among vendors and a consensus was formed that it does not have the flexibility to capture the benefit of innovative technologies.

A consistent view emerged that RFPs are appropriate for commodity-based items; however, the RFP is unable to cater to innovative technology as the purchasers may be unaware of its existence and subsequently cannot have appropriately weighted criteria.

“A blanket procurement process should not be applied to innovative technologies, especially when the medical device industry is driven by innovation”, a vendor stated.

One vendor spoke about a contract they were secured in for three years and had full support from their purchaser (scoring 100% on the key performance index), but when the time came to reapply for the contract, they were unable to secure the position due to the RFP process.

Another vendor thought it was clear that the RFP has no allocation for past performance, and while this may be a way to attempt to eliminate bias amongst purchasers, it does not take into account the rapport that the vendor has established and their product rating.

Overall, the RFP process can deter the incentive for companies to become innovative, and this could lead to serious consequences in the future for the medical device industry.

**F. End User Disconnect**

The lack of communication between vendors and end users was another theme that emerged from the organizations that were interviewed. Vendors felt that the competitive advantage to drive innovation comes from communication with end users. However, GPOs and SSOs were inhibiting the relationship.

One vendor stated, “We would love to have clinicians tell us ‘this is the tool I need, can you create this?’” However, because of the guidelines surrounding vendors and end-users interaction, these simple yet crucial questions cannot be addressed. This lack of communication can lead vendors to becoming less innovative, or of greater concern, going out of business.

Another vendor addressed this issue with the question, “Why develop a new product if you know you are not going to be able to get its approval within the medical community?” It was widely perceived that the lack of end-user and vendor communication hinders the ability to produce new technology. Though it is
acknowledged that this was eliminated in order to make a more fair and transparent tendering process, it also eliminates innovation in the medical device industry.

3) Has centralized tendering affected your business in terms of developing and enhancing products?

The next interview question also generated a lot of discussion, with the consensus being that the GPO/SSO tendering model created an impediment to developing and enhancing products. The comments generally were clustered around access to GPOs and end users, the complexity and bureaucracy of the RFP process, and the rigidity of the RFP process.

A. Access

One vendor indicated that if a market can be penetrated and a relationship established with the GPOs, then feedback can be acquired from end-users. That expedites the product maturation cycle and assists with product evolution. If the vendor is not part of the GPO, then they not going to get feedback, which is necessary to refine the product.

Another vendor stated that the rise of GPOs and SSOs has done nothing to help them. Generally the small companies are at the bottom of their list in terms of asking suppliers to bid and having a chance to get the business.

Another vendor stated that they have no dealings with GPOs. He said he cannot get them to return calls, and cannot make any in-roads with them.

B. Complexity

A second theme that was raised was that the RFP process was now highly complex and laden with bureaucratic requirements.

One vendor stated: “We (as an SME) do not have any advantages in terms of the tendering process from GPOs. They seem to be germinating in somebody’s office all across Canada... every couple of months you see a new GPO coming out. They all claim to be saving all kinds of money for their region (which is false), what is the public going to do because they don’t know anything about it.”

Others complained that the tendering documents were too long and that the requirements to complete the proposal were unduly onerous.

C. Rigidity
A common issue raised was that the RFP requirements offered little flexibility to adapt to reviewing truly innovative technology.

One vendor indicated that there were some differences between Ontario and Quebec in this regard: He stated:

“If I’m in Quebec, if you take a innovative technology and they are in a position where they can adopt new technology and do not need the RFP, if you are the manufacturer of one of those technologies, you can work the key stakeholders, and they are in a position to accept it without having to go through the formal process, in Ontario, they are so concerned about following the implied directives and they lose sight of this.”

Another vendor suggested that this was now a ‘process’ and that they generally make the decision not to go through that process. He argued that the rigidity of the process does not truly allow firms to market new technology.

4) What are the most significant challenges in terms of managing the tendering process for the sale of medical devices in Canada?

Again this was a very wide-ranging discussion that generated a great deal of material. And again, the main themes in terms of the challenges of managing the tendering process were around access, complexity and rigidity.

A. Access

Without having direct contacts with those who are involved from the purchasing side, many found getting up-to-date information on RFPs was challenging. It should be noted that all RFPs are posted on websites, but a significant monitoring effort from SMEs is required to remain abreast of upcoming opportunities.

One respondent indicated that GPOs and SSOs needed to be aware of one’s company to compete in RFPs.

Another firm had taken to contracting out monitoring of RFPs to have relevant competitions forwarded to them.

One vendor indicated that the biggest challenge is getting a foot in the door. He said that they have missed opportunities because they were not aware that a pertinent RFP was on-going.
Another vendor suggested that there was no coordination between the vendor and the actual user (the surgeon), with the implication being that the GPO/SSO was impeding the vendor’s access to users.

Another vendor complained that to enter into the RFP process it is necessary to have $1 million of liability insurance, which costs $30-35K per year for insurance coverage. This is a barrier to enter the bidding process.

Another vendor complained that the GPO/SSO process was almost like it was done deliberately to eliminate the small players. The physicians, nurses and technicians can no longer see sales representatives because the hospital has a contract with a GPO.

One vendor stated:

“In my view, the GPOs and the province of Ontario would like to cut down the number of purchase orders they make. We will send out a broad tender that a multinational will carry, and the little guy is shut out because he can’t provide everything.”

Another vendor suggested that the GPO/SSO model was driving them to increasingly move their focus abroad. If they are going to develop something new, they go outside Canada.

One vendor opined:

“From my experience, if I go back 10 years ago, when you would get a request from a physician, nurse or technician to look at possibly making a widget, your ears would automatically get attention and you would definitely talk to them to figure out their needs and how they can develop that in their own structure. You would go back to your engineers and within two months, you would have a widget to show, which would then make it to the market. Nowadays that is gone. We do not get those opportunities anymore. First of all you cannot enter the hospital anymore, your sales rep have to fight to get into the hospital (“we are Medbuy/HealthPro hospital”). Major barriers to get to the users like you used to. They just locked the whole industry from gaining some more opportunities for manufacturing in Canada.”

**B. Complexity**

There was a consensus that the centralized tendering model is unnecessarily complex and that SMEs find this complexity a challenge to manage.

One vendor complained that each GPO uses a different template and they do not resemble each other. Each province has different mandate and different questions.
GPOs and SSOs make it very difficult for the SMEs to participate, suggesting that this model works best for firms that have significant resources to dedicate to managing these RFPs.

Another vendor stated: “Instead of having the way it used to be and we can compare from what we used to fill out in terms of forms and now with the GPOs you are looking at 50 plus pages to fill out, which is the standard form.”

This vendor went on to say that if the form is not entirely completed, the GPO/SSO will use a rating/percentage for each line, which makes the bid less competitive. This firm has gone as far as hiring an individual dedicated to responding to RFPs. This has been advantageous because once they have responded to a few RFPs they can see commonalities in their requirements.

On vendor argued that the level of complexity forced firms out of the market. He stated:

“We raised that at the provincial level when we met with them and I raised it with the federal government. We had several meetings with them (provincial and federal governments), but nothing changed, it is still the same. It leaves out many companies that can just not afford to participate [in RFPs].”

Another vendor argued that GPOs/SSOs increase the costs of doing business. And those costs are driven up with the use of the tendering process. The cost burden increases.

C. Rigidity

One vendor complained that in addition to managing the RFP process, there were other bureaucratic burdens. For instance, Health Canada must also be contacted (takes 90 days) if you are adjusting your product.

One vendor stated:

“There aren’t many clauses that allow you to open the door, you must push your way in. There needs to be more appropriate and new technology clauses to invite a company in, which could be a huge benefit later on.”

And he went on to say:

“A lot of these processes are procedurally directed and this process does not allow for new dialogue. If you break the process, then you are not being fair to everybody.”
This respondent argued that there needed to be a new technology clause in RFPs that would make the uptake of novel technologies compulsory among health device purchasers and that this would need to be externally funded with new monies.

5) Do you think the tendering/procurement policies or practices have affected your ability to enter into new markets? Please elaborate.

The main theme introduced here was access. In response to earlier questions, many firms indicated that breaking into new markets was a challenge and that there was a perception that cracking the GPO/SSOs is difficult. So much so, that some firms ceased to pursue this business.

In response to the question, one respondent said:

“Definitely - in the sense that we make a conscious decision not to enter certain markets. We are an established organization that deals with every hospital in Canada, they already have some contact information with their members and it’s not a black and white barrier. We can only go to so many places and to try and sell our technology.”

Another vendor opined that most of the small companies in this sector are run by entrepreneurs who saw a business opportunity several years ago and pursued it. Today that is just not happening because of the mentality, “why should I do that if I can’t sell it?”

Another respondent indicated that this is a different approach to doing business, and that the GPO/SSO approach tends to concentrate risk. Firms that are successful in the RFP process get large contracts, while others get little or nothing. Unsuccessful bidders often struggle to maintain a presence in these markets until the next round of RFPs. This reinforces the ‘win-big, lose-big’ characterization of the market described earlier.

Other respondents described the challenges of remaining abreast of tendering opportunities and lamented the instances when viable RFP opportunities were missed. They noted that if an important opportunity were missed it was difficult to subsequently get into this market, since the duration of the awarded contract tended to be at least three years.
6) Are there differences in tendering and procurement policies and practices in Ontario and Quebec? Can you describe these differences? Is it easier to conduct business in Ontario or Quebec? Please elaborate?

Most respondents did not identify one province or the other as being a particularly different from one another in terms of ease of doing business.

One respondent indicated that both Ontario and Quebec are difficult to penetrate - if you are not on the participating list, it is very difficult to get in.

One respondent stated:

“Quebec is RFP dependent. Quebec is really tough.”

One respondent suggested there was a language barrier with Quebec not issuing RFPs in English. To respond to an RFP, the firm has to hire a translator. Despite making numerous requests to the Quebec government, this firm has been unable to get translated RFP documents provided to them. As such, they no longer pursue business in Quebec.

Another vendor noted that the RFP process was more transparent in Quebec, with all RFP respondents being able to see the winning bid, and as such, losing bidders get an opportunity to gain valuable feedback on how their proposal fell short.

Another vendor indicated the Quebec RFPs tended to be less ‘bundled’ meaning that firms could bid on a relatively small (or even a single) item. RFPs from Ontario tended to group together related devices, which made it more challenging for a firm that did not manufacture or distribute the entire product line. This makes it challenging for SMEs who may produce a very narrow product line.

Another respondent indicated that in Quebec, there seemed to be a greater willingness to ‘do a deal’. This individual reported that rather than go by a rigid RFP process that senior managers within the health sector were eager to negotiate and to try to get the best products in use.

7) Do you have any additional thoughts on the tendering/RFP process for medical devices in Canada?

Most respondents chose to reinforce the points they made earlier in the interview. These again, can be highlighted under the themes ‘Complexity’, ‘Access’, ‘Rigidity’, and ‘Buy Canadian’.

A. Complexity
Reiterating a common theme, one vendor complained:

“Well do they have to send out 100 page documents? The basic outline for the RFP is the same in any deal. Just tell us what you want and it would make it a lot easier. We spend a lot of time doing a MedBuy or HealthPRO response.”

Another thought there was a lack of coordination between purchasers:

“The problem is the SSOs. Their thought patterns are not consistent”

**B. Access**

One vendor returned to the issue of contract length. He stated:

“... Many of the contracts that are signed with multinational companies are for multiple years. Once the contract is signed, the door is locked. So you cannot sell any of your products to these hospitals. If it is going to be run by GPOs, it should be a shorter contract so other SMEs can compete. To not sell your product for five years, you get to a point where you go outside of Canada or shut down your company. Contracts should be a shorter duration.”

**C. Rigidity**

Multiple vendors pointed out that the GPO/SSO model tended to treat its members as having equivalent needs. There was some concern that if members had different needs, these unique requirements may not be met by the device ultimately selected from the RFP responses.

One vendor suggested:

Government could give some of the mandate back to the organizations (meaning RHAs). In Ontario, for example, there are limitations of various products. Better guidance for the materials management people on how to interpret these limitations and greater flexibility to opt out would be desirable. He stated: “The government can’t have a cookie cutter approach. There needs to be flexibility in the process to account for real differences in products/technology.”

Another vendor offered a similar view:

“There is the ability for those decisions to be skewed based on representation at the GPO/SSO. How do (individual hospitals) prevent their needs from being hijacked?”
D. ‘Buy Canadian’

There was a consensus that there needs to be a greater weighting assigned to being Canadian. If Canadian firms are unable to match the technical specifications of international bidders, then this is reasonable, but if a Canadian product is as effective, a preference weighting should be given to the domestic firm.

One vendor stated:

“There has to be some sort of preference weighting that is given to the Canadian companies to compete or to be inclusive in GPO initiatives.”

And another vendor offered a similar view:

“It if is developed and supported within the country and then go to outside markets by export, and on taxes alone, everyone benefits. It is a matter of will and policy supporting Canadian business.”

8) How do you think procurement practices affect the development of innovative technologies? How could this be improved?

A number of key themes emerged in the discussion around how innovation among Canadian firms could be better supported.

A recurrent theme was, again, that the lack of access to clinicians and end-users was a significant impediment to innovation. The second theme that was raised again was that more support needed to be offered to Canadian firms trying to do business in Canada.

A. Access

One vendor stated:

“We would love to have clinicians say: ‘This is the tool I need. This would help me. Build me this tool. If I could convince my hospital administrator one or two or ten and all of my colleagues would then want to buy them.’”

Another voiced a similar viewpoint:

“In this past week, I sat down with my new manager and R & D staff. I told him we are blocked from hospitals from going in and talking to clinicians. We have to figure out what technology clinicians need. The manager is going to contact the director of community services, and see if they can meet, and go over some of the challenges they have at the home level. The communities they reached out to both responded
well to the manager. They wanted the help from them, and in turn the company gets to develop more novel products. “

And yet another offered a similar view:

“[We need to] have a more concise gateway to the user. There needs to be a better way of access to encourage product development. [This lack of access] puts up another barrier that the small companies are not well enough equipped to review the documents. “

Another vendor suggested that it was necessary to increase the interface between clinicians and vendors. “The way that a hospital does procurement is a little bit empathically, they are procuring physical products by going through a catalogue of the kinds of items on the market, but wouldn’t it be great if they could say, “I want to solve this particular medical imaging problem”, “I have a big backup with x-rays in ER, so instead of buying a bunch of x-rays, maybe a company has a solution to that problem with a high technology medical device. We need to buy solutions, rather than off the shelf products”.

Another simply stated:

“It boils down to one word: ‘access’“. 

B. Increased Emphasis on ‘Buying Canadian’

There was a general sense of frustration that the rigidity of the tendering process allowed little or no room for purchasers to deliberately ‘buy Canadian’.

A respondent summarized his views by saying:

“We have no advantage being a Canadian company, and in some cases, we are disadvantaged.”

One respondent suggested more strategic sourcing and developing a better inventory of what Canadian firms are doing, might help to keep more business in Canada.

Another respondent suggested:

“Let’s at least have a process to see whether something made in Canada does exist and set up an infrastructure to see whether it can be made in Canada. Make it part of government’s thought process. What are we buying from abroad? And if we are buying products from abroad, do we have a Canadian manufacturer that produces these products? If not do we have the infrastructure to support this?”
Another respondent said:

“We are buying a lot of stuff that is not made in Canada, and there is no reason why we can’t make it here, and in some cases, we are making it here and its not making its way to end users.”

And another respondent suggested:

“Government has to play a role, you may be saving a little more by buying outside of Canada, but spending 5-10% more on a Canadian product, then we are investing in the Canadian economy and creating jobs.”

Finally one respondent indicated that more grant money for research and development would be useful. He stated:

“If you’re a SME and coming up with innovation means you spread the cost to your entire company. Anything we have done, we have had to spread the cost over the business, you get a tax break from the feds, but it would nice to get some grant money”

So a number of key themes emerged and respondents tended to be remarkably similar in their views that GPO/SSO purchasing model was not a good trend for their business primarily because this approach was unnecessarily bureaucratic and rigid, and because it reduced access to firms. In terms of fostering innovation, most firms believed that the process was not conducive for the uptake of new and novel technologies and that lack of access to clinical end-users was a significant impediment to the innovation process.

The GPOs, SSOs and an Advocacy Group's Perspective

“All industry needs is a clear commercial pathway, and that a customer is at the end of it”, Gail Garland, President and CEO of OBIO stated.

OBIO (Ontario Bioscience Industry Organization) is a private sector, membership based organization that is an advocate for Ontario’s life science sector. Its overall goal is to deliver more innovative products and services to a global market (OBIO, 2012).

In the medical device industry, the current climate of cost-saving reductions leaves little incentive for organizations to invest in innovative technology. OBIO argues that legislation needs to be established that supports and mandates the implementation of innovative technology. OBIO is involved with developing a strategy in attempt to drive the industry forward, with one of their initiatives relating directly to innovation adoption and procurement. According to Garland, there are a number of jurisdictions that implement policy at the systems level, for example: Sweden’s policy requires that 2% of hospital budgets must be allowed to procurement of new
devices that have not been implemented last year, and the Netherlands’ policy requires that the new technologies entering the hospital must supersede the use of the old ones. These are the type of policies OBIO feels would help make a clear commercial pathway.

A few SSOs and MedBuy (GPO) provided a different perspective on the procurement process in Ontario. The SSOs supported the notion that the new procurement directives, as well as their companies were not inhibiting innovation but that it was the purchasers’ inability to make an effective internal business case, and the vendors’ inability to sell their technology on paper. MedBuy supports the view surrounding how organizations are unable to properly acquire innovative technology due to a lack of understanding of the RFP process. They have sponsored many conferences to bring together end-users and vendors, and to bring awareness relating to the process of initiating an RFP. An SSO stated, “It will take a few years for organizations to flush out the process”, meaning that health care organizations need to become more familiar determining appropriate scoring questions and weightings of the RFP in order to obtain the innovation that their association requires.

An SSO identified a process they used called “Vision Sessions” in order to bring together end-users and vendors. The conversation is regulated in the meetings; however, vendors are able to ask questions pertaining to what products clinicians need, and what products would help make them more effective. They are not allowed to gather insider information, and certain information discussed in these sessions may disqualify vendors from the RFP bidding process. This session is an initial step from an SSO to try and collaborate end-users with vendors.

Another challenge of implementing innovative technology into hospital sectors is that one department will have to allocate budget to the innovative product, while another department may benefit from it. Because departments’ budgets are separate (or ‘siloed’), it becomes less advantageous to purchase new technology. This comment was echoed by another advocate, who argued that silo budgets were detrimental to the uptake of novel technologies. Silo budgets mean the department paying for the device that will not benefit from future savings, ergo they will not be inclined to pay for it, even though it may save the organization money and result in a better patient outcome. Procurement needs to take a system view, rather than focus on specific departmental budgets.

Another theme was that the RFP process typically did not include health technology assessments (HTA) on medical devices. This means that a superior, but perhaps marginally more expensive device that would offer good value for money may be overlooked because the review process (and the criteria for device selection) may not adequately assess this device.
5. Innovation in Medical Devices – an Opportunity Lost for Canada?

Technological innovation implies the creation, development, use and diffusion of a new product, process or service and the significant technological changes of the product. (Technalia, 2012)

A recent report by the Conference Board of Canada examined the role of procurement in fostering innovation. The author demonstrated that Canada lags behind other OECD countries in terms of strategically utilizing procurement to fund innovation. Given the climate of rising costs, RHAs have increasingly utilized GPOs or have organized into Shared Service Organizations (SSOs) to coordinate purchase of medical devices. The Conference Board paper argues that the coordination of purchases may have driven the costs of purchasing medical devices lower, however, this may have come with a significant trade-off: a loss in innovation.

When purchasing was more fragmented and widely distributed this gave opportunities for SMEs in the medical device industry to gain a market presence – often through partnerships with clinicians. While there was undoubtedly some abuse in this system – there is a well-documented literature on the influence of physician preference items on purchase decisions of RHAs – it may be that creating a barrier between the end-user and the entrepreneur impedes the development of novel technologies that would address the needs of clinicians.

As the market is now increasingly concentrated, individuals or groups of physicians have very little impact on purchasing decisions. This has also made it more difficult for SMEs to actively pursue RFPs if they are unable to service RFPs that may include RHAs from across Canada. As such, these SMEs are finding it increasingly difficult to access markets.

SMEs have been shown to be important sources of product innovation and increasing concentration of the medical device market among large firms may be limiting Canada’s potential to develop disruptive technologies.

Despite the concentration of purchasing power through GPOs and more efforts to coordinate drug review, with an increasing reliance on cost-effectiveness and value for money, health expenditure continues to rise at an unsustainable rate. At the very time when we need game changing technology – devices and products that will change how citizens interface and interact with the health care system – we are seeing the firms with the potential to develop these technologies being squeezed from the market.

Most standard models of firm organic growth involve the SME breaking into their local or regional market and using this as an opportunity to expand and achieve economies of scale and gradually grow into national and international players in their chosen market. However, by restricting responses to competitive tenders to
firms that can supply on a large, multi-institutional scale as represented by a GPO’s members, this may effectively eliminate small and medium sized firms from getting into this market. This may further result in firms that could have developed innovative new products (and potentially been significant players in the international market) being unable to reach their potential.

**Models of Innovation**

To further examine the role of innovation we conducted a brief review of models or templates of product innovation. Below are three schematic diagrams of how product innovation occurs.

**Model 1**

![Diagram showing the relationship between desirable to users, possible with technology, and viable in the marketplace.](TROeMAR, 2012)
A consistent element in the development of innovative products is identifying demand and integrating external ideas and feedback throughout the development process. This involves examining user need and identifying possible opportunities to leverage existing technologies. End users may be given opportunities to trial prototypes and to suggest modifications to improve functionality. Furthermore end-users can act as product champions and encourage uptake and utilization.
However the GPO/SSO model of procurement has largely resulted in reducing the role of local end users in procurement decisions. The result is that one of the key channels of innovation remains untapped and under-utilized.

A common message that emerged from the interviews with SMEs is that access to end-users (i.e. clinicians) is difficult and the opportunities for true collaboration are minimal.

Warren and Susman (2004) identify the cultural attributes of successful innovative enterprises. Of relevance here, they argue that engagement with customers and the willingness to take risks are key drivers of becoming an innovative firm. However, the current emphasis towards larger national tenders and separation of firms and purchasers greatly reduces the ability of firms to engage with customers (or potential customers). Furthermore, the trend towards a relatively small number of vendors winning large national or provincial RFPs reduces the willingness of firms to take risk in new product developments.

6. Discussion

In this section we highlight a number of themes that have emerged in this research and explore possible policy directions for procurement of medical devices in Canada.

**GPOs/SSOs are potentially constraining growth of SMEs in the Medical Device Industry in Canada**

The overwhelming view of the respondents was that GPOs and SSOs are an impediment to growth of Canadian firms. The bureaucratic and rigid nature of the process results in a number of SMEs choosing to limit or selectively engage with the RFPs. In addition, SMEs find new product development difficult because they do not have a dynamic dialogue with end-users. As a result, new technologies may not be developed.

**GPOs and SSOs are a Barrier to Entry**

Discussions with representatives from smaller firms in the medical device industry indicated that GPOs might be restricting their opportunities to get a toe-hold in the Canadian market. Typically, GPO tenders are broad in scope meaning they need to serve a large and geographically dispersed market (which may be critical when products are complex and require intensive training and support). Vendors that cannot guarantee this level of support may not be invited to participate in the tender, or if they are able to respond to tenders, will be eliminated because they lack the scale to service the dispersed GPO members.
The RFP Process is too Rigid and Bureaucratic

A point that was raised by all the vendors interviewed as well as from the advocacy organizations and the GPOs/SSOs was that the rigidity of the RFP process could result in developing RFP scoring frameworks that would not effectively accommodate novel technologies. It is important that the framework be flexible and sufficiently reactive that when emergent technologies are tendered, special consideration be given. Increased fairness, transparency and accountability are important, but these features should not come at the expense of foregoing cost effective technologies that could significantly improve patient outcomes.

At least some discretion needs to be given to health authorities to adapt and experiment with new technologies. Preferably, the ideas being promoted in Ontario that will legislate the mandatory adoption of novel health technologies by RHAs will be successfully implemented.

There may be merit in looking at different RFP approaches when there is potentially disruptive technology available. Mature technologies, where there is limited capacity for technology to enhance health outcomes could be managed through a more straightforward tendering process. Products that are potentially innovated would be classified as high technology.

Where possible, GPOs and SSOs should seek to develop common tender templates and there should be a concerted effort to reduce the administrative burden of completing RFP documents. Current practice tends to result in increased burden on many firms, to the point where some firms choose to not engage in tendering.

Being Canadian Should Matter

A theme raised by all SMEs and by most individuals who have a role in supporting the medical device industry is that there is no advantage to being Canadian when responding to Canadian RFPs. This was a source of some frustration, as many respondents believed their businesses contributed to the Canadian economy by employing people in good (high-skilled, well-paying) jobs and they paid Canadian corporate tax. They believed that there should be some incentive for GPOs and SSOs to ‘Buy Canadian’, however, this seemed to be superseded by a mandate to minimize short run costs.
**Track Record Should Matter**

Firms that have successfully provided medical devices in the past should be rewarded for their past successes. Transitioning from one technology to another may not be seamless, and as a result, bonus points should be awarded in new tenders to vendors that have successfully delivered goods and services to a particular RHA in the past. A theme that emerged from some vendors was that a track-record of providing high-performing devices and exemplary service was not rewarded in subsequent RFP processes.

**Need to Separate Medical ‘Commodities’ from ‘High-Technology’ Medical Devices**

The movement towards centralized purchasing will undoubtedly bring benefits and cost savings for mature items where there is limited technology or where there is limited capacity for innovation to bring substantial improvements in patient outcomes and improve the efficiency of health care delivery. However, in the high-technology segment of the market – where product innovation can be substantial and there is potential for significant improvement in patient outcomes (or where patient outcomes can be preserved at a significant reduction in cost) a different tendering process is required. In the high technology segment the process needs to be much more flexible.

**Contract Duration Should be as Short as Possible**

While recognizing that a longer duration may have some advantages for the purchaser and the firm if they are required to make a substantial strategic commitment to meet the terms of the contract, contract durations should be limited to their shortest possible duration. This serves numerous purposes. First, it allows for the more rapid uptake of new technology as it becomes available. Second, if there are innovations in production that lower manufacturing costs, the purchaser can take advantage of these and finally, it may provide more opportunities for firms who have been previously unsuccessful in the bidding process.

**In the Longer Term the GPO/SSP Procurement Model May Result in Higher Prices**

In the effort to reduce costs and achieve greater efficiencies in the short run (which may favour centralized purchasing through GPOs) we may be trading off longer-term efficiencies that could be gained if smaller firms were given more opportunities to grab a niche of the market. It may also be that having a relatively small number of firms be successful in RFPs results in oligopolies emerging. This may have the longer-term effect of increasing prices for medical devices due to a lack of competition. Many SME respondents suggested that the GPO/SSO
procurement model made staying in business difficult. Since there were relatively fewer channels through which products could be sold and contract durations tend to be long, there can be long periods where there are very few market opportunities. Many individuals from advocacy groups indicated that this inhibits a vibrant and competitive market and may lead to longer-term cost increases.

**Transparency Matters**

One theme that emerged from several vendors was that the lack of transparency in RFP outcomes was detrimental. For firms to become more competitive they need to know what aspects of their proposals were weak and how they could be improved in the future. While issues around price transparency limit full disclosure of RFP outcomes, Canadian firms would benefit from knowing where they lack competitiveness.

**Recommendations Towards a Program of Innovation**

McKinsey & Company (2008) ranked developed countries in terms of innovation, placing Canada 13th out of 17. Similarly the Conference Board of Canada places Canada 14th out of 17. However, as a nation, we dedicate a great deal of resources to basic R&D and have leading universities that are at the forefront in the creation of new knowledge. Where we lag is in commercializing research – going from the lab to the market. The medical device industry is a segment where we could potentially improve on this poor showing. However to do so, will require policies that encourage (or make compulsory) the uptake of innovative technologies in the health sector.

The Conference Board (2011) report highlights the successes that have occurred in the UK as a result using procurement to play a more strategic role in innovation. ‘What gets rewarded gets done’ is their mantra this is undoubtedly true.

While there are undoubtedly benefits in increasing monopsony power in purchasing, some effort and coordination needs to be taken to encourage Canadian firms to develop innovative new technologies that have the potential to change the way Canadians interface and utilize the health care system. In addition to promoting greater preventative measures, these are our best hopes of maintaining a single-payer universal health care system.

To do this, SMEs must be incentivized to develop new technologies in partnership with local RHAs. Echoing the call of the Conference Board, coordination should come from the Government of Canada (perhaps through Industry Canada).

A common complaint from vendors during the interviews was that there was no channel through which innovative products could be brought to market. If there is
no way to bring a product to market, then it is difficult for firms to invest in and develop new products. We would argue that a market structure that discourages innovation – particularly when new products could save money and improve patient well-being – is misguided.

We observe an inconsistent direction from governments on this issue. Medical device firms are encouraged to be innovative and to invest in R&D and to seek breakthrough disruptive technologies. This encouragement comes from Ministries of Industry and Economic Development. However, the directive from Ministries of Finance and Health is to contain costs, and this usually means forgoing innovative and more expensive technologies in favour of cheaper and more mature products. There is no point in developing an innovative product if there is no market for it.

**Shared Risks - Shared Rewards**

Developing and purchasing innovative technology is risky for both vendors and firms. RHAs are not encouraged to take risks in procurement and as a result there is limited incentive for firms to develop novel technologies as the potential for uptake is uncertain. An area that has not been explored carefully is to try align the risk-and reward incentives through Public-Private Partnerships between SMEs and RHAs with matched funding from the federal government.

**Firms Need to Re-engage with Clinicians and Practitioners**

Business models need to be developed in which firms can re-engage with practitioners and clinicians. Technological innovation needs to be more directly tied to anticipated health care needs. While the dialogue sessions that are sponsored by GPOs and SSOs are undoubtedly useful, the process of innovation requires more dynamic interplay between entrepreneurs and end-users. As highlighted earlier, virtually every model of product innovation points to the generation of ideas and the direct interaction with end-users as playing a key role in moving innovation from the lab to generate a commercialization opportunity.

Snowdon, et al. (2010) argue that physicians need to be re-engaged in the procurement process. One of the outcomes of increased centralization of purchasing has been to marginalize the role of practicing physicians in procurement decisions. Physicians and other practitioners need to collaborate more closely with entrepreneurs to conceive and develop the game changing technology the health system needs.

What gets rewarded gets done – building on the work of the Conference Board of Canada, if Canada is serious about increasing the uptake of innovative technologies, then new funding will needed to be earmarked to encourage this. Current levels of health funding are insufficient to encourage the uptake of new technologies that
may be more expensive in the short-run, but which could be considerably more cost effective in the longer term. OBIO, among others, is leading an effort to get legislation in place that would require health authorities to purchase novel technologies. However, it remains vital that RHAs purchase the right technologies. So the emphasis should be on buying products that have the greatest long term potential to fundamentally change how (and how often) patients interact with the health care system. It should also give some preference (to the extent that trade agreements will allow) to Canadian firms and Industry Canada should seek to identify firms and technologies that could be disruptive.

Snowdon et al. (2010) make two important conclusions that we wholeheartedly endorse. First, they argue that health practitioners need to be engaged with product developers much earlier in the innovation cycle. The second key point is that purchasers need to be engaged in early proof-of-concept testing. Vendors need a natural outlet to test the viability of their innovative products. This must occur through hospitals and health authorities. Snowdon et al. describe this as a ‘fail early, fail cheap’ strategy, which will allow vendors to get a critical early view of the viability of new technologies. This will provide a crucial filter in the innovation process that will separate products with true market potential from those that will not be successful at a much earlier stage in the innovation cycle, thus allowing vendors a better chance to develop marketable innovation.

This is consistent with the models of innovation described earlier, each of which indicated that an end-user's perspective was critical throughout the product development process and is particularly vital in the idea generation and product development phase. In discussions with one GPO, the respondent indicated that vendors often struggled to make a good business case with their technology. While it may be superior, they need to demonstrate that it offers superior value either in terms of better patient outcomes or by reducing costs elsewhere in the health system. Engaged practitioners can facilitate this. Furthermore, this speaks to an expanded role for independent HTA analysis to evaluate new technologies for their potential to improve patient outcomes and improve efficiency in health care delivery.

Robinson (2008) also concludes that physicians are central to the uptake of new technologies. Furthermore Pauly and Burns (2008) calculate that research surrounding physician generated devices are far more cited than devices generated by others, suggesting that they generate more interest and have a greater chance of being widely accepted and having a significant impact.

**Increased Local Discretion and Greater Partnerships Between Industry and RHAs**

To develop truly innovative technologies that meet key health care needs, local health authorities need discretion and empowerment to forge partnerships with firms. Similar to the role that health authorities play in educating health
professionals, health authorities need to be more engaged with firms in the medical device industry to develop relevant technologies that will have market potential.

The Conference Board of Canada (2011) made four recommendations for improving the uptake of innovative technologies in Canada. They recommended:

1. Federal leadership is needed and suggested a National Health Innovation Office could be created to identify promising new technologies and encourage (or subsidize) their uptake.

2. Targeted funding is necessary to encourage RHAs to adopt new and potentially risky technologies.

3. Regional innovation hubs should be supported – these would encourage entrepreneurs and end-users to collaborate on product development.

4. A change in culture and attitudes is needed – innovative technologies need to be embraced and end-users need to interact with entrepreneurs.

We believe these are all important ideas and would encourage the federal government to give these recommendations thorough consideration.

**The Role of the Federal Government**

One of the recurrent themes – particularly among those who support the medical device industry – is that there is a role for the federal government to play in this industry. A number of ideas emerged:

- Make the purchase of innovative (and potentially disruptive) technologies a requirement for all RHAs.

- Play a greater coordinating role in identifying areas where Canadian firms could compete with international firms in supplying medical devices to RHAs.

- Provide more funding to RHAs to purchase innovative medical technologies.

- Provide more funding through grants and tax concessions to SMEs developing innovative and potentially disruptive technologies. Grants should
be conditional on firms having committed partnerships from clinicians and RHAs

- Provide analytical expertise (perhaps through the Canadian Agency for Drugs and Technologies in Health) to help identify potentially disruptive technologies.

- Ensure that there is a market for innovative technologies.

Although the main objective of this line of questioning was to examine what role the Canadian Government can play in fostering the medical device industry, the comments did suggest a misunderstanding of the roles of various levels of government in the provision of healthcare to Canadians. Devices are approved and regulated by Health Canada but their purchase is a provincial issue that goes right down to individual health authorities. While many of the ideas are worthwhile, implementation will require coordination between Federal and Provincial governments and regional health authorities.

7. Conclusion

Coordinating Canadian health policy is particularly challenging, given the separate and distinct roles of the federal and provincial governments. Health care is co-financed by the federal and provincial governments, with pharmaceuticals and medical devices regulated and approved by the federal government. However, health care is delivered by provincial governments (or Regional Health Authorities who are accountable to provincial Ministries of Health). As such coordinating any policy mechanisms directed toward encouraging more flexibility in procurement, increased emphasis on innovation and trying to support Canadian firms has to be conducted within the broader federal framework.

The Drummond report recommended that Health Quality Ontario expand their mandate to become a regulatory body to establish and govern evidence-based directives to guide treatment decisions and OHIP coverage. Health Quality Ontario directly impacts the medical device industry by making recommendations for the industry based on scientific evidence. It is further emphasized in this document that particular focus needs to be placed on ensuring that innovation is not diminished by directives that are unreasonably rigid. To achieve this goal, it is recommended that effective input be acquired from key stakeholders including physicians and effective liaisons be established with quality/research organizations in other provinces and the federal government. (Ministry of Finance, 2012)

Different provinces have different capacities to pay for innovation and to experiment with the use of novel technologies and leading edge firms (or potentially
leading edge firms) tend to be clustered around major research nodes in the country. And the flexibility to favour Canadian firms in procurement must not violate existing trade agreements, which may classify these actions as anti-competitive.

Canada has invested heavily in basic research, yet the track record of commercializing this research into successful business ventures is poor. What is required is a more strategic view of research and its importance. In order to maximize our return on investment, these technologies must find their way to market. There is no doubt that this will require more strategic thinking and behavior from all levels of government with particular leadership from the Federal Government to generate a vision of an innovation driven health care system. This will also require local autonomy to allow organic partnerships between practitioners and entrepreneurs to flourish.

If this can be achieved, the enormous potential of the medical device industry to both deliver better health care for Canadians and the advancement of world leading industry can be reached.
APPENDIX A

25 Mandatory BPS Requirements *Copied* from Broader Public Sector Procurement Directive Document
1) Segregation of duties

- Must have 5 roles (requisition, budgeting, commitment, receipt, and payment)
- Responsibility must lie with different individuals
- External auditor must be in place for small organisations

2) Approval authority

- Goods and non-consulting services
  - Approval authority schedule (AAS) must be established for procurement of goods and non-consulting services
  - AAS must be approved by board of directors of organization
  - All procurement must be approved by AAS

3) Competitive procurement thresholds

- Procurement process must be in place for goods and services over $100,000 dollars. Procurement of goods must be as follows:

<table>
<thead>
<tr>
<th>Total Procurement Value</th>
<th>Means of Procurement</th>
<th>Recommended/Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0 up to but not including $100</td>
<td>Petty cash</td>
<td>Recommended</td>
</tr>
<tr>
<td>$100 up to but not including $3,000</td>
<td>Procurement card (P-card)</td>
<td>Recommended</td>
</tr>
<tr>
<td>$3,000 up to but not including $10,000</td>
<td>Purchase order</td>
<td>Recommended</td>
</tr>
<tr>
<td>$10,000 up to but not including $100,000</td>
<td>Invitational competitive procurement (minimum of three suppliers are invited to submit a bid)</td>
<td>Required</td>
</tr>
<tr>
<td>$100,000 or more</td>
<td>Open competitive process</td>
<td>Required</td>
</tr>
</tbody>
</table>

- Organizations are not allowed to decrease the value of procurement by separating one procurement into multiple in order to avoid means of procurement.

4) Information gathering

- Request for Information (RFI) and Request for Expression of Interest (RFEI) may be requested at the discretion of the organization obtaining procurement; however, this information may not be used to bias the vendors in any way.

5) Supplier pre-qualification

- Request for Supplier Qualification (RFQS) allows organizations to pre-qualify suppliers based on their capabilities and qualifications
6) Posting competitive procurement documents

- Open competitive procurements must be made available through electronic tendering system available to all Canadian suppliers

7) Timelines for posting competitive procurement documents

- 15 calendar days is the minimum response time that organizations must provide suppliers for open competitive procurements (over $100,000)

8) Bid receipt

- Competitive procurement documents must contain a bid submission date and closing time, any bids submitted afterwards must be returned unopened.

9) Evaluation criteria

- All evaluation criteria must be finalized prior to commencement of the competitive procurement process
- Must outline mandatory, rated, and other criteria that will be used to evaluate submissions, including weight of each criterion
- Can only be altered by means of an addendum to the competitive procurement documents

10) Evaluation process disclosure

- Organizations must fully disclose the evaluation methodology and process to be used in assessing submissions
- Must state criteria that will disqualify a supplier from the bid

11) Evaluation team

- Must have an evaluation team in place that has signed a conflict-of-interest declaration and non-disclosure information agreement

12) Evaluation matrix

- Each team member is required to complete an evaluation matrix rating the submissions

13) Winning bid

- Highest score received is the winning bid

14) Non-discrimination
• Organizations cannot discriminate or give preferential treatment to a supplier in a competitive process

15) Executing the contract

• Agreement between organization and successful supplier must be formally defined in a signed written contract before the provision of supplying goods or services commences

16) Establishing the contract

• Contract must be finalized in terms of the agreement that was released with the procurement documents

17) Termination clauses

• All contracts must include appropriate termination clauses

18) Terms of agreement modifications

• The term of agreement modifications must be set out in the competitive procurement document
• Extending the agreement beyond that set out in the competitive procurement document amounts to non-competitive procurement

19) Contract award notification

• Contract award notification must be posed for procurement of over $100,000

20) Supplier debriefing

• Within 60 days are receiving an unsuccessful bid, suppliers are allowed to request a debriefing with the organization

21) Non-competitive procurement

• It is recommended that organizations employ a competitive process to achieve optimum value for money
• Non-competitive procurement may be used as outlined above

22) Contract management

• Payments must be made in accordance with contract
• Assignments must be properly documented
• Dispute resolution processes should be included in the competitive procurement document
23) Procurement records retention

- All procurement documentation must be kept for 7 years

24) Conflict of interest

- Any conflict of interest must be evaluated and then mitigated appropriately

25) Bid dispute resolution

- Bid dispute resolution must be outlined in competitive procurement documents
APPENDIX B

SSOs and GPOs Operating in Ontario and Quebec

ONTARIO:

GPOs

Medbuy
Health pro

SSOs

Plexxus – serves the 12 largest hospitals in the GTA
HMMS-London ON
Champlain – Ottawa
3SO- Kingston and surrounding area hospitals
Northwest supply chain- 13 hospitals in northwestern Ontario
Procure- Windsor
COHPA- Central Ontario healthcare procurement alliance

QUEBEC:

Le Groupe d’approvisionnement en commun de l’Est du Québec - Section Bas-Saint-Laurent, Gaspésie, Îles-de-la-Madeleine,
Le Groupe d’approvisionnement en commun de l’Est du Québec Section Saguenay - Lac-St-Jean / Nord-du-Québec
Le Groupe d’approvisionnement en commun de l’Est du Québec - section Québec / Chaudière-Appalaches
Le Groupe d’approvisionnement en commun de l’Est du Québec - Section Mauricie/Centre-du-Quebec
Le Groupe d’approvisionnement en commun de l’Est-du-Québec - section Estrie

Le Groupe D’approvisionnement en commun de l’Est du Québec section Côte-Nord

La Corporation du réseau de la santé et des services sociaux de l’Outaouais (CARSSSO)
Le Groupe d’approvisionnement en commun du Nord-Ouest du Québec - secteur Abitibi-Témiscamingue
Le Groupe d’approvisionnement en commun du Nord-Ouest du Québec - secteur Laurentides-Lanaudière
SigmaSante
Le Groupe d'approvisionnement du Montérégie

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Appendix 10

Health Systems Should Buy Better - Fiona Miller
OPINION: Health systems should buy better

by Fiona Alice Miller
February 3, 2016

Few of us think much about how hospitals and other health care organizations buy the products used to provide patient care – everything from MRI machines to bandages.

Recently, however, policy makers at the federal and provincial levels have started taking an interest in how we buy – or procure – in the health sector, suggesting a need to reform these systems to ensure the adoption of innovations and support “economic prosperity.”

As a health policy professor who has spent time studying procurement arrangements across several Canadian provinces, I see numerous opportunities to improve procurement in the health care sector. Unfortunately, it’s not clear that the reforms proposed by the federal and provincial governments will fix what’s broken.

Governments have been pushing procurement to produce savings in the health sector since at least the mid-1990s, with steady moves to aggregate spending through joint buying groups across and within provinces and territories. While bulk purchasing can be useful, the buying culture that’s emerged has prioritized upfront costs above other considerations.

Lately, however, industry representatives and clinicians have been pushing back on the focus on purchasing price in some areas. Both in Canada and internationally, the focus for offerings like medical devices and ehealth technologies is increasingly on forwarding “innovation” and “strategic procurement.” Unfortunately, it’s business-as-usual for everything else – meaning that hospitals continue to emphasize low upfront costs when it comes to everyday items like bed linens.

Consider the lowly diaper, which no one would consider a health “innovation.” And yet when I asked a patient advocate about procurement recently, “diapers” was the item she cared about. In my research, I have found that for products like diapers, health care organizations tend to buy the ones that offer the lowest upfront cost while meeting minimum requirements.

But saving on upfront costs doesn’t mean saving on costs – a cheap diaper may cost more because of the labour required to change patients more frequently or to change and wash bed linen in the event of leakage. As well, paying higher costs on such “lowly” items could lead to better patient outcomes – a more comfortable and better fitting diaper may encourage patients to be more mobile and socially active. Reformed procurement systems should take into account not just the upfront cost of an item but its long-term value, whether novel and innovative, or old and ordinary.
Another problem with current procurement reform efforts is their narrow focus on economic benefits. It makes sense to consider how investments in health systems – which now take nearly 50% of provincial budgets – can contribute to local industries, but why stop there? Leading health systems like Kaiser Permanente have implemented environmentally preferable purchasing programs – buying products with fewer negative impacts on the environment or human health. This should be a natural for the health sector, given its massive environmental footprint. Another natural interest should be human rights and ethical procurement. The British Medical Association has been active in supporting “fair medical trade.” And spurred by the efforts of a committed surgeon, the English NHS began to require that suppliers actively manage labour standards for products where the risks of worker abuse and child labour are significant, beginning with surgical instruments. Reformed procurement systems – described in various guides – should support markets that not only provide opportunities for economic development, but also demand fair labour practices and ensure low carbon.

The health care sector should stop focussing on products that are cheap and instead focus on products that bring value – inside and outside health care. Value can come in the form of better outcomes, reduced nursing requirements or increased patient satisfaction. Value might also come from providing a home market for Canadian firms and supporting the development of a vibrant health products industry. Value should also come from combating slavery and environmental degradation.

The truth is, procurement has long been seen as a “back office” support function, whose value lies in reducing costs so that money may be redirected to “front line” care. As well, procurement by governments and within the broader public sector is highly regulated to conform with the rules of trade law and policy. Intra-national trade agreements, provincial legislation and directives, and court judgments uphold rules whose purpose is to make public sector buying opportunities open to global companies, not to make them responsive to local needs. For example, international trade laws mean that Canadian hospitals aren’t permitted to favour Canadian companies.

There are significant problems to be overcome before health care procurement can live up to its potential. The health sector will have to play a much bigger role in policy debates about the legal framework that governs public sector purchasing. Legislation may need to change, and buying arrangements be reformed. But one of the biggest challenges may be just thinking differently about what procurement is actually for. To paraphrase the UK Sustainable Procurement Task Force, “too often the business side of healthcare – the purchasing, the employment, fails to reflect the policy goals of healthcare. The result – a sector that misses opportunities to do more to lead by example to achieve its own policy goals.” We need to start seeing procurement in health care not as simply buying products, but as buying health – healthy environments, healthy economies and healthy people.

Fiona Alice Miller is a professor of health policy at the Institute of Health Policy, Management & Evaluation at the University of Toronto and director of the Division of Health Policy & Ethics at the Toronto Health Economics and Technology Assessment (THETA) Collaborative.