

# 2009 ACCOMPLISHMENTS & ACTIVITIES

## 2009 A Landmark Year for MEDEC

### Extension of our national reach

In 2009 MEDEC continued to extend its national reach through the organization's merger with a Quebec medical technology association to form MEDEC-AITS. MEDEC-AITS is now our Quebec Division. MEDEC-AITS has two staff members - Diane Côté, VP, MEDEC-AITS and Claudia Ouellet, Communications and Special Projects Manager. Since the merger, MEDEC activities in Quebec continue to grow. This year, MEDEC also welcomed Robert (Bob) Rauscher to focus efforts on policy and corporate affairs in Western Canada. Since adding this new resource we have extended our collaborative efforts in Western Canada. MEDEC hosted a meeting in Vancouver with the BC Health Authority's (HA) Shared Services Organization (SSO). Some 160 industry members heard from the SSO about its new processes. Members were able to ask specific questions about provincial tenders and provided suggestions to the BC HA SSO on process issues.

### Ontario PET Scan Decision

The Ontario government's decision to add Positron Emission Tomography (PET) technology to the services covered by the Ontario Health Insurance Plan (OHIP) is applaudable. The government's decision came after repeated requests from MEDEC and other stakeholders to ease access to PET technology in Ontario. MEDEC had repeatedly stressed that the province's restrictive access to PET technology has disadvantaged Ontario residents who needed access to PET scans for appropriate diagnosis and treatment and created a disparity between access to health care in Ontario as opposed to other provinces.

### ESA Regulation

MEDEC successfully challenged *Ontario Regulation 438/07* showing it as a replication of regulations already existing at the Federal level under the *Medical Devices Regulations*. Regulation 438/07 required that medical device companies report adverse events to the Electrical Safety Authority (ESA) and register as manufacturers with the ESA. MEDEC requested that medical device companies be exempt from the regulation. The Ontario Ministry of Consumer Services in turn acknowledged the precedence of the *Medical Devices Regulations* and concluded ESA has no legal basis for requiring 'Manufacturer Registrations' or a 'Registration Fee'. In July, ESA acknowledged our concerns and advised manufacturers of their decision to postpone the August 30, 2009 deadline for the registration program.

### Membership Survey

MEDEC conducted its annual membership survey in the second quarter of the year. The survey had a 17 per cent response rate with approximately 43 full MEDEC member companies (up from 30 in 2008) participating. Active members continue to be satisfied with their MEDEC membership. The results show that 100% of members are satisfied or somewhat satisfied (up 2 per cent from 2008 and 6% from 2007). The survey identified the top five industry issues as the Tendering Process; access to new Medical Device Technology; Health System Reform; Corporate Compliance; Health Technology Assessment.

### MDB Wait Times

MEDEC met with Health Canada's Therapeutic Products Directorate (TPD) and Medical Devices Bureau (MDB) to ask for action on the declining performance in application review times. We specifically requested establishment of a joint MEDEC/TPD task force to look for ways to streamline the application and review processes; an additional 18 full-time employees to eliminate the backlog; and recognition of the work of other global regulatory authorities that meet Canadian standards. MEDEC also sent a letter to Supriya Sharma, Director General, TPD on these issues. The messages highlighted in the letter will be used in other government relations initiatives.

### Appointment to Federal Government Advisory Board

MEDEC was appointed to the Federal Government's Department of Foreign Affairs and International Trade Life Science Advisory Board. The mandate of the Advisory Board is to provide strategic and tactical advice on the exporting, importing, and investments for medical technology. The Board meets quarterly.

### Provincial HTA Board Representation

MEDEC represents the industry on the Ontario Health Technology Advisory Committee (OHTAC) Board. MEDEC was invited to join the Alberta Advisory Committee on Health Technology. MEDEC represented the industry at a government Stakeholder Forum on Alberta Health Technologies Decision Process in September. We outlined the industry's position on health technology assessment (HTA) to the 40 participants and engaged in lively discussion on how to follow HTA best practices to ensure patients get timely access to medical technology.

### Patient Safety and Single Use Medical Devices



The reuse of single use devices is a serious issue for MEDEC and our members. Our position is that the reuse of single use medical devices should be banned until Health Canada ensures the safety, effectiveness and quality of the reused device. MEDEC wrote to the Minister of Health in New Brunswick requesting a withdrawal of the Ministry's Request for Proposal for a third party reprocessor over concerns for patient safety. Patients in Canada are not protected by regulations in Canada and their right to informed consent is not being honoured. MEDEC believes if patients were informed about the practice of reuse of single use medical devices, they would not provide consent for themselves or their family members.



### GHTF International Conference

MEDEC hosted the 12th Global Harmonization Task Force Conference in downtown Toronto from May 12 - 14 under the theme, "Realizing the Value of Technology." Over 300 participants from 36 countries attended including regulators, consultants, and medical technology associations and businesses. Health Canada is the current Chair of the GHTF and Stephen Dibert, MEDEC President and CEO is the current Vice-Chair.

### Golf Tournament

The sold-out 31st annual Golf Tournament took place in June at the Royal Ontario Golf Club in Hornby, Ontario. Approximately 100 members attended the event.

### Competition Law Workshop

With the amendments to the Competition Act, MEDEC joined with Osler, Hoskin and Harcourt to host a Q & A session to update MEDEC members on the changes to the Act. Approximately 20 members attended the workshop.

### Meetings on Tendering

MEDEC scheduled three training sessions on Tendering to inform members about the new procurement legislation, *Bill 17*, in Quebec and the new tendering processes flowing out of the legislation. The first session was jointly hosted with the Quebec Supplier Healthcare Association and Quebec's Ministry of Health and Social Services. Two other sessions were held in Toronto (58 participants) and Montreal (31 participants) to train member companies on how to use the Contract A and Contract B templates used in the Request for Proposal process. The training documents (French and English versions) are available on the members-only section of MEDEC's website at [http://www.medec.org/tendering\\_task\\_force](http://www.medec.org/tendering_task_force).

### Market Authorization Workshop

MEDEC held a Market Authorization Workshop in Ottawa in September. More than 80 regulatory affairs personnel from a variety of medical device companies attended the workshop. The workshop looked at managing applications, administrative processing, application validation and the quality of license applications. IVDDs, Class III and IV medical devices, license amendments, significant changes and STED documents were also covered.

### Access and Reimbursement Conference

MEDEC hosted an Access and Reimbursement Conference on September 23, 2009. Attendees heard from experts in access and reimbursement on these topics - health technology assessments for medical technologies; group purchasing and hospital decision-making; technology acquisition processes; tendering and RFPs; group purchasing benefits; stakeholder advocacy and government relations. Seventy-five per cent of the respondents rated the conference program as excellent.

### Board Meeting and Inflection Point Conference

On September 29, MEDEC held its Board of Directors' meeting at the École de technologie supérieure in Montreal. Following the meeting, an event called *Inflection Point* hosted by MEDEC showcased two keynote speakers: Dr. Pavel Hamet, personalized medicine specialist and Mr. Léonard Aucoin, Project Manager for the creation of INESSS, the new health technology and drug assessment body for Quebec.

### New Board President

Mr. Jim Wilson, Vice President, Clinical Research and Government Affairs, Biomet International has been appointed Chair of MEDEC's Board of Directors. An accomplished executive with over 30 years experience in the medical device industry, Jim has worked vigorously on MEDEC committees. He has chaired the Orthopaedic Committee, the Value of Technology Committee, and sat on other MEDEC committees such as the Code of Conduct Committee. He is also a founder of the Canadian Orthopaedic Care Strategy Group.

### Six New Board Members Appointed

This year, six new members were appointed - Gerry Stefanatos - Vice-President, Canada & Latin America, Hospira Healthcare Corporation (2<sup>nd</sup> term); Vafa Jamali - Vice President, General Manager, COVIDIEN; Doug Grant - Vice President Public Policy & Communications, Bayer Healthcare; Paul Bradley - Executive Business Director, Johnson & Johnson Medical Products; Scott Kadwell - Director, Business Development, Sorin Group Canada and John Simmons - General Manager, KCI Medical Canada Inc.

### Letter to Canada Revenue Agency

MEDEC and the Diagnostics Committee sent a letter to the Canada Revenue Agency (CRA) requesting a review and issuance of a guidance on the *Le Gardeur tax ruling* in order to provide consistency and clarity to the vendors and customers in the medical diagnostic technology industry. Customers are using the ruling as the basis for claiming GST/HST exempt status on some, but not all diagnostic products. MEDEC also arranged for two speakers from CRA to present on GST, the tax ruling process and upcoming HST changes.

### Increase in Membership

MEDEC experienced a 25 per cent increase in membership in 2009 with twenty-five new companies joining our association.

### HR Compensation Survey

Several of our member companies participated in our annual compensation survey done jointly with Mercer. Members who participated in the survey enjoyed complimentary access in 2009 to Mercer's Human Resources Policies and Practices database, which captures key policy information on items such as training, incentive design and benefits prevalence.