

FOR IMMEDIATE RELEASE

MEDEC Commends the Auditor General of Canada for its Report

(TORONTO, June 10, 2011) With the release on June 9, 2011 of the Auditor General's Report on Health Canada's Medical Device Program, MEDEC applauds the Office of the Auditor General (OAG) of Canada for its ongoing efforts to ensure that the Medical Device Program meets its obligations to provide timely access to medical technology and fulfills its commitments to improve the program. MEDEC also commends the efforts of Health Canada in attempting to meet the recommendations and commitments of past audits. MEDEC endeavors to collaborate with Health Canada on issues of mutual interest and has seen progress in our joint efforts.

The OAG report clearly shows that Health Canada is not fully meeting its obligations in relation to medical devices. Defining clear targets and actions would adequately address the nature of medical devices which are substantially different to drugs or pharmaceutical products. There is more work to be done and MEDEC looks forward to continuing to work with Health Canada to resolve these issues.

The medical device industry has ongoing challenges with Health Canada's performance on the time it takes to make decisions on applications for medical devices. Our members see first-hand how the delays affect the care provided by healthcare professionals to Canadians. While we are aware of the challenges the Department has had in resourcing its medical device program, we feel that there are other means to address issues related to the delays which affect Canadians' access to products.

The OAG refers to one of these means - greater cooperation with foreign regulatory bodies. The MEDEC position is that by expanding, and accelerating international cooperation, delays in reviews can be significantly reduced. For example, products that are already approved and

marketed in the United States or Europe should have an expedited and streamlined process for Health Canada review and approval.

While the OAG reports that Health Canada has significantly expanded its post-market activities, MEDEC noted that Health Canada still faces challenges in meeting its requirements.

MEDEC supports the expanded post-market activity of Health Canada and will look for ways to enhance our support.

MEDEC will continue to work with Health Canada to ensure patients in Canada get timely access to safe, proven medical technologies that improve health outcomes and improve the lives of Canadians.

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.