



**MEDEC**

CANADA'S MEDICAL TECHNOLOGY COMPANIES

LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIES MÉDICALES

***Health/Bio-sciences Economic Strategy Table  
MEDEC Response to Questions for Stakeholders***

**May 18, 2018**

MEDEC is the national association representing Canada's innovative medical technology (MedTech) industry. We represent over 100 MedTech companies (ranging from Canadian-owned to multinationals) and work closely with the federal and provincial-territorial governments, health professionals, patients and other stakeholders to deliver a patient-centred, safe, accessible, innovative and sustainable universal healthcare system supported by the use of medical technology.

MEDEC believes that the MedTech sector could significantly contribute to driving domestic economic activity, job creation, increasing foreign direct investment (FDI) and improving health outcomes. Our goal is to establish Canada as a global leader in medical technologies, with an economy that attracts significant FDI while spurring exports to promising global markets. A strong collaboration between the public & private sectors is critical if we are to reach this goal.

### *1) What is your aspirational vision for your sector? What would success look like in 2025?*

#### Vision:

- Canada should utilize technology to support economic growth by being in the Top 10 globally in attracting **clinical trials** (per capita), **medical device exports** (per capita) and **R&D spend**. This would result in hundreds of millions of dollars in new FDI and thousands of new jobs.
- Canada should utilize technology to support improved patient outcomes by having 75% of Canadians who want, and are able to access, **digitally-enabled healthcare services** to be able to do so (e.g. Personal Health Records, e-prescriptions, e-visits, remote monitoring, patient portals, etc.).

- **MedTech MNEs spend a significant amount of dollars globally on R&D.** US and European MedTech industry revenue grew 5% to more than US\$364B in 2016 and total R&D spending by pure play MedTech companies also rose 5% in 2016 to US\$27B.<sup>1</sup> **Medical Device R&D investment in Canada from MNE's is currently below US\$100M (1.4% of revenues) which is well below the world average where investment in Medical Device R&D hovers around 7% of revenues.**<sup>2</sup> This low level of investment can be tied to a Canadian landscape that has an outdated and fractured provincial procurement environment and a product approval regime that is both burdensome and lacks predictability, making it extremely challenging for industry to bring new and innovative technologies to market. Solving for these systemic issues is instrumental to driving Canadian R&D investment to be on par globally.

The investment in Canada should be at US\$500M at a minimum, and would not be unreasonable in the US\$750M range. An audacious vision for R&D spending would have Canada punching above its weight, with initiatives designed and implemented to incentivize MedTech companies to spend their R&D dollars in Canada. Such a policy would provide numerous economic spillover benefits, including employment.

In this context, the federal government could also initiate several small, but not insignificant, changes to lessen administrative burden and enhance process efficiencies in the market.

- MedTech MNE's have a stronger financial capacity to invest in innovation than home-grown SME's. The capacity of Canadian SME's to increase R&D spend is closely tied to their ability to generate revenue from both domestic and export sales. In 2016, Canada's GERD (Gross

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<sup>1</sup> Statista

<sup>2</sup> Statista

Domestic Expenditures on R&D)/GDP was at 1.6% as compared to the OECD average of 2.4%.<sup>3</sup> To bring GERD/GDP up to the OECD average, Canada would need to spend \$10B more on R&D annually; of this, private industry would be asked to contribute roughly \$5B (51%). While MNE's can contribute strongly to this number, Canadian SME's will also need to commit their fair share of R&D dollars; this can only occur if SME's are able to generate increased export sales.

Given that the MedTech sector invested almost 7% of revenues in R&D globally, twice the average of industry in aggregate, a focus on MedTech will reap more significant rewards for the government vs. other sectors.

**2) It is often suggested that countries need to target their growth efforts towards areas of competitive advantage. In your sector, where does Canada have strength or emerging strength?**

Canada is uniquely positioned to impact the life sciences landscape because of our numerous strengths:

- Canada has the talent to win: A highly-educated population that is both growing and diverse in nature.

- Access to Big Data that is also Diverse Data: Canada has access to vast amounts of data due to a health system where the payer and the provider are the same; this provides us with a unique opportunity in the collection of patient data. Our publicly funded health system has created large data sets – data sets that are goldmines for researchers, clinicians and innovators (e.g. AI developers).

- Strong industry partnerships with academia.
- Academic leaders clustered in a small handful of key centers.
- Academic & clinical institutions that have pioneered many global approaches in modern medicine.
- Integration within the global supply chain.

**3) What are the obstacles to innovation in your sector? (You may wish to think about investment, talent and skills, access to markets, rules or regulations, demand.) How could these be overcome?**

- **Simply put, the market for MedTech in Canada is not nearly as attractive as markets in other jurisdictions.** This makes it difficult for Canadian subsidiaries of MNE's to advocate for Canada's share of investment in R&D spending and new product launches, and extremely challenging for our home-grown SME's who struggle to access global markets when they cannot point to their home market as an early adopter. If we can address unfavourable market

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<sup>3</sup> An Analysis of Budget 2018: Research, Innovation and Trade, Global Advantage Consulting Group Inc., March 2018

conditions in Canada, the rapid life cycles of MedTech products gives industry the ability to make relatively nimble investment decisions in R&D and manufacturing.

- MedTech companies will invest in jurisdictions where they can bring innovations to market quickly, and where those products will be adopted by the health system. Canada is not one of those jurisdictions. We are competing for global investments and there are jurisdictions globally where the government has acknowledged its role in enabling innovation adoption and have done an excellent job of coordinating fully aligned, state sponsored stakeholder strategies.

This has made those systems – Germany, Belgium, Singapore and Netherlands to name a few – countries where total Medical Device exports are a multiple of the local market. While countries such as the Netherlands and Belgium enjoy exports of US\$18B and US\$13B respectively in comparison to their local markets of US\$4B and US\$3.5B, Canada's exports are underperforming at one-quarter of our total USD\$6.7B local market.

The benefits these countries are experiencing aren't limited to providing patients with access to better care, but also include driving economic activity through increased local investment by the very innovators looking to get their technologies adopted.

- Canada should be a leading power in a host of life sciences activities from clinical trials to R&D and manufacturing. We've been held back however, by our reluctance to adopt the kind of demand-side policies that commit resources to pulling innovations into our healthcare system that we've already applied in priority areas like renewable energy. **If we're going to tap into that potential, then we need to collectively shift our mindset and begin to view healthcare as an economic driver rather than a cost center.** This is an opportunity to unleash our significant healthcare budgets to not only improve patient outcomes and increase system efficiencies, but to stimulate technological innovation. We should aspire to having a system that simultaneously improves patient outcomes, allows patients timely access and drives the economy.

- If we want to compete globally and position Canada as a worldwide leader, we first must ensure the **alignment of all stakeholders**. From the regulatory agencies to the government payers and funders, from the policy makers and the healthcare providers to industry, consensus and a common will to move forward in the same direction is required. Only then will innovation adoption bodies and procurement agencies have the clear and specific direction they need to move forward with value-based procurement.
- **Opportunity to Align Regulatory Initiatives with the Innovation Agenda:** Health Canada's recent regulatory initiatives such as Cost Recovery and challenges with the implementation of the Medical Devices Single Audit Program (MDSAP) run counter to the innovation agenda as do the slow approval times to license a medical device in Canada. Slow regulatory approval times for medical technologies is a disincentive for companies wanting to introduce innovative technology in Canada, wanting to invest in Canadian R&D, or wanting to export Canadian developed technologies since many countries require licensing approval to be obtained first in a company's home country. The cumulative effect of regulatory initiatives

such as these negatively impacts the positive effect of federal innovation initiatives. The positive signals coming from Health Canada recently in these areas must follow-through to action.

- **MEDEC believes that the Canadian regulatory environment for medical devices can be improved to support an innovative economy in the short-term.** Health Canada could be a significant enabler by working with the Ministry of Innovation, Science and Economic Development (ISED) and Global Affairs Canada, as well as industry, to successfully grow the medical technology sector while at the same time helping to improve health outcomes and health care system sustainability. Initiatives such as the Regulatory Review of Drugs and Devices (R2D2) should be encouraged as opportunities to simplify regulatory regulations and improve system efficiency to allow timely access to drugs and devices. A new approach to the approval and adoption of innovative medical technologies would enable growth for the sector and deliver better patient outcomes.

#### ***4) What is, or will be, the most significant innovation globally in your sector for the next 10 years? What is needed to capitalize on this innovation and establish Canada as a world leader?***

There are four specific segments which we would like to highlight where we anticipate a double-digit CAGR over the next several years and where there are already established foundational clusters:

- One area where advanced economies like Canada can have an advantage is in the **integration of diagnostic imaging technologies with guided imaging, robotics, and artificial/augmented intelligence.** This is reflected in the work currently being done in the existing clusters. A good example of this in Canada is Toronto-headquartered Synaptive Medical whose technology combines surgical planning and navigation, robotic automation, digital microscopy and informatics in a fully integrated platform. A report from *Research and Markets* states that the current Global Healthcare Robotics market is valued at US\$6.3B (2016) and is expected to grow at a CAGR of 22% to US\$20.6B by 2021.
- A second area is **point of care (POC) in vitro diagnostic devices (IVDDs).** The demand exists for these technologies, and with a shift to value-based procurement and investment in key technology areas, Canada's healthcare spend could pull a significant amount of Canadian-based innovation into the supply chain. A report from *Research and Markets* states that the current Global POC market is valued at US\$21.4B (2016) and is expected to grow at a CAGR of 10% to US\$38.1B by 2022.
- A third area is **Artificial Intelligence (AI).** With three AI hubs located in Montréal, Toronto-Waterloo and Edmonton, Canada is poised to realize the immense promise of AI for improving medical decision-making in diagnostics, prognosis, indirect patient care such as optimized hospital workflows and improved inventory management. It will also be of value in home care where wearable devices and sensors will be used to assess and predict patient needs. A report from *BIS Research* states that the current Global Healthcare AI market is expected to grow at a CAGR of 50% to US\$50B by 2027. (Note: while there is a bit more variability

between research houses regarding the growth of AI in healthcare, all estimate a double-digit CAGR).

- Lastly, there is **Connected Health**, also known as **Connected Medicine or Technology Enabled Care (TEC)**. Connected Health means different things to different people; for the purposes of this submission, Connected Health refers to opportunities for medical devices to allow patients to engage with clinicians and to better self-manage their care. As such, Connected Health encompasses programs in telehealth, remote care (driving the move to home healthcare services), and is associated with efforts to improve chronic care. Canada is a leader in Connected Health. There are many good reasons for this, one of which is our historical legacy of innovation and investment in telecommunications. In Canada, rural and remote communities represent about 20% of the nation's total population. Though small, given that Canada has the world's second largest land mass, the social and economic cost of delivering on the promise of the Canada Health Act and transporting individuals to urban centres for examinations, tests, therapies and surgeries, is immense. The only way to achieve this in an affordable and effective manner is with the most technologically advanced, connected medical devices. A report from *Grandview Research* estimates the **Global Connected Health** market is expected to grow at a CAGR of 25% to US\$612B by 2024.

What is needed to capitalize on these four established innovation areas:

- **Pan Canadian Health Organizations (PCHOs)** must function as effective and efficient enablers within these four segments by collaborating with industry to develop commercial offerings that are viewed as providing "Value" in global markets.
- Health Canada must enhance the **predictability of medical technology approvals** and become a leader in efficiency by decreasing the bureaucratic burden while enhancing effectiveness.
- The **Canadian Trade Commissioner Service** has a role to play in leveraging their understanding and expertise of value in world markets, how to efficiently enter different markets as well as market predictability.

***5) To ensure that all Canadians benefit from accelerated economic growth, what actions and partnerships could businesses, educational institutions, governments, and Canadians undertake?***

- The Federal Government should take a leadership role through the adoption of the International Consortium on Health Outcomes Measurement (ICHOM) standards.

ICHOM has developed a common framework for health outcomes measurement that allows health systems to compare how they are performing versus their peers. A lack of common standard for health outcomes measurement is certainly not unique to Canada, but the recent work by ICHOM is a big leap forward. Other countries, such as the Netherlands are already adopting such an approach.

From an economic perspective, this would encourage innovators to develop technologies and solutions that will provide the most meaningful benefits to patients. This would be particularly useful for small and medium sized enterprises as they could develop their technologies and

better understand how they can create value propositions throughout the globe. Moreover, if the Federal Government begins to collect outcomes in accordance with ICHOM standards, it could develop a globally envied framework and database that would harmonize outcomes measurement across all disease state across the entire country.

Finally, having a standardized approach to measuring health outcomes can help the health system create greater efficiencies since they will better understand what value they are receiving from the scarce dollars they are spending. Those savings could be re-invested into better health care, new innovations, or supporting a healthy and robust health economy – a virtuous cycle.

- **Case Study: Regenerative Medicine in Japan** - Removing regulatory barriers to build an innovation economy

**Japan wants to be the regenerative medicine center of the world and is creating new opportunities in the field of regenerative medicine through government support and regulatory reform.**

Over the past 5 years, Japan built a regenerative medicine (“Regen”) cluster which has led to the following outcomes:

- Japan’s rapidly aging population benefits from the health improvements.
- Japan participated in 6 international Regen clinical trials in 2012. By 2016, Japan was leading 40 International Regen Trials.
- Japan’s Regen market will be worth an estimated US\$30B by 2030.
- Since 2014, there have been a flood of partnerships (including research collaborations with Japanese universities), research studies, licensing deals and new regen opportunities. This initiative has attracted domestic company investment including large Japanese companies (e.g. Takeda, Fujifilm) purchasing SME innovations as well as foreign investment through distribution agreements (e.g. Canada’s RepliCel)

In 2012, Japan won a Nobel prize for regenerative medicine and, a year later, announced a strategy to build their domestic industry. Prime Minister Shinzō Abe’s government committed to invest \$1B over 10 years to this effort. The “Abenomics” growth strategy included changing the regulatory pathway for Stem Cell therapy research & commercial approval and provided full commercial access (with reimbursement) to the Japanese market within 3.5 years vs. the normal timeframe of 10 years. The HTA benefits for each therapy must be proven within 7 years or reimbursement will be lost.

Creating competitive regulatory environments to attract significant foreign investments while simultaneously becoming effective receptors of innovation are strategies currently being employed by Germany, Sweden, Denmark, Australia and the United States. We would strongly recommend that Canada adopt a similar strategy.