Medtech and the Future: Canada as a Global Leader in Advancing Health Care and Innovation

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Issue

The Canadian medtech sector faces many barriers that have pushed both Canadian and international investors to seek opportunities elsewhere, affecting Canada's ability to effectively foster innovation, benefit from significant opportunities such as succeeding in foreign markets and attracting foreign capital, and becoming a global leader in technology innovation and healthcare advancement.

Background

There is a great opportunity for Canada to foster its world-class innovation and expand its economic, political and social potential by strategically investing in the medical technology (medtech) sector (OPTIMUS 2017). Medical technology can be defined as "the application of science to develop solutions to health problems or issues such as the prevention or delay of onset of diseases or the promotion and monitoring of good health" (Tulchinsky and Varavikova 2014). An international tech strategy, which should include a long-term framework to guide R&D, manufacturing and commercialization, would position Canadian medtech companies to better succeed in foreign markets and attract foreign capital (Fraser 2022).

The medtech sector is a competitive and growing industry valued at $456 billion and has contributed immense value to health care and improved the lives of millions globally (EY Canada 2020). In 2021 alone, Canada spent $20 billion importing medical devices from other countries (Medtech Canada 2021a). Canada has the infrastructure and capacity within its post-secondary institutions (PSIs) to produce world-class science and technology innovations; however, strategic partnerships and investments are still needed to facilitate the transfer and fostering of innovation into domestic and international markets (Dooks 2021). Medtech can support Canada's 2030 Agenda National Strategy that invests in science, innovation, technology and partnerships to accelerate progress toward achieving the UN Sustainable Development Goals (Government of Canada 2019a).

Why Medtech?

The COVID-19 pandemic exposed major gaps in Canada's health care sector that resulted in delays in vaccine procurement (Alin et al. 2022). Depleted stockpiles of personal protective equipment also corresponded with the unprecedented decline in surgical supplies, MRI, CT and X-ray machines (Leo 2020; Medtech Canada 2022). The high demand and low supply of medical equipment and supplies resulted in a heavy reliance on China and has created an urgent need for current and future medtech innovation (Leo 2020; Medtech Canada 2021b). The Canadian medtech industry has been acutely aware of these challenges and the impacts they could have on the health care sector.

Roadblocks Standing Between Canadian Medtech Innovation and the Global Market

Currently, Canada houses a significant amount of valuable medtech expertise and innovation; however, when it comes to driving innovation from the lab to the market, there are barriers in the way (OPTIMUS 2017). Some of the most significant barriers include long waiting periods for intellectual property (IP), new coding applications, trial periods and reimbursement processes, high costs of development and lack of funding, lack of market expertise and opportunities, high risk and short technology lifespan, and lack of sufficient access to verification and protection over IP rights (ibid.).

Protection of Intellectual Property and National Security

With Canada being a highly developed mixed-market system, a reliable and monetized system of IP through successful licensing is an important mechanism that can enhance national security (Shivakumar 2022). Without these critical structures in place, countries looking to dominate and replicate advanced technologies, such as medtech, can easily threaten Canadian IP (ibid.). These barriers have directly impacted the high risks of investing in medtech within Canada, which has significantly reduced the potential of Canadian medtech innovation, commercialization and the significant achievements of high-ranking institutions (OPTIMUS 2017).

Emerging fields of technology, such as medtech, have become key drivers of economic growth and development. This growth has also given rise to new and serious national security vulnerabilities that are emanating through a range of entry points into Canada's economy (Government of Canada 2021). Foreign multinational companies are starting to take note of Canada's higher education achievements and are profiting from the IP of Canadian university R&D programs. Canadian universities must take national security into consideration when partnering with foreign entities (Snyder 2019; Marijan 2021). A technology strategy must ensure that Canada manages the magnitude and complexity of these threats while also ensuring that the economy remains open, competitive and innovative (Government of Canada 2021). Medical devices make up a cross-sectoral industry that relies heavily on IP. For firms conducting business internationally while developing more advanced technologies and products, an effective IP strategy, especially on patents, is critical in gaining a competitive advantage in international markets (Government of Canada 2020).

Procurement Processes

Canada faces significant barriers in the procurement process that have led to medtech companies finding it increasingly difficult to get devices approved for use in domestic and international markets. Canada currently uses a model of conducting health technology assessments to inform policy makers around the introduction and diffusion of health technology. This is a lengthy process that takes over a year in a best-case scenario; in fact, many devices take several years to receive approval (MacNeil et al. 2019). By the time these assessments are completed, the priorities of policy makers have often shifted, leading to additional time needed for a medical device to be approved. In a 2016 survey of Ontario's 23 academic hospitals, 76 percent of respondents reported procurement regulations as a "major hurdle" to adopting innovations within their hospitals (Kirkwood 2019).

Moreover, the culture surrounding the adoption and implementation of new medical devices in Canada is risk-averse, focusing primarily on cost containment and not necessarily on value for money (ibid.). Focusing on short-term costs impedes innovation and does not encourage growth in the medtech sector. Other jurisdictions, such as the Netherlands and other European countries, use a value-based procurement (VBP) system that focuses on improved patient/operational outcomes and savings to the larger healthcare sector (Medtech Canada 2021c). Although it involves more upfront costs, there is evidence that it provides long-term savings for governments and healthcare providers (ibid.).

Opportunities

Knowledge Mobilization

Canadian PSIs graduate a significant number of professionals each year who could support innovation. In terms of share of PSI graduates among the working-age population, Canada has the highest proportion of workers who have completed post-secondary education among nations in the Organisation for Economic Co-operation and Development (OECD) (55.2 percent). There are more qualified engineers in the labour force in Canada than in

any other G7 country, and Canada is first in the G7 for higher-education sector R&D performance (Government of Canada 2019). Thus, it is essential that the IP produced in Canada's universities is not only protected but also harnessed to economically benefit from it.

The process through which the benefits of university teaching and research is spread to society is known as "knowledge mobilization" and includes not only generating new patents and licensing revenue, but also providing new technologies and research-based solutions to SMEs (Universities Canada 2017, 2). Research shows that there is a positive interaction between innovation and exports: as firms export more, they also tend to innovate more (De Fuentes, Niosi and Peerally 2020). Supporting growth of operations abroad and trade outside of Canada spurs innovation, in turn granting companies increased capacity to integrate themselves into international markets. Global Affairs Canada (GAC) has much to gain by creating a tech strategy that is innovation-focused. This would lead to significant return on the investments the Trade Commissioner Service is making in international business partnerships.

In-licensing, Non-dilutive Funding and Technology Transfer Offices

Canada has the capacity and initiative to further develop and foster Canadian innovation through in-licensing, which is "the process of creating a contract that allows another firm to provide capital to the development and commercialization process, while taking on the majority of the financial responsibility" (Two Labs 2018). In-licensing has proven to be very successful for tech start-ups which have significantly supported Canadian innovation (Government of Canada 2022). In-licensing can provide a steppingstone for medtech start-ups to break into the global market while ensuring individual ownership and captivating the intrinsic market knowledge of Canadian tech firms (NIBUSINESS 2021).

The benefits that in-licensing provides include significant reduction in the time and cost of development, lower risk, longer technology lifespan, a means to meet the market standard and the freedom to operate with consistent ownership of IP (Hickey, Barrow and Harris 2018). In-licensing can be best complemented by non-dilutive funding that "does not require any equity stakes or ownership in a company" (Two Labs 2018). A provision of non-dilutive matching grants by the Federal Government of Canada for Canadian firms willing to provide in-licensing can add great value to GAC's mandate of providing an essential foundation to leverage Canadian innovation to the next level.

In-licensing processes can also be strengthened by Canadian university tech transfer offices (TTOs) and tech incubators. TTOs and tech incubators have the capacity to ensure quality IP and act as channels between medtech innovation and international markets (University of Waterloo 2022). They also play a major role in negotiating challenging and time-consuming IP agreements (MacNeil et al. 2019). The goal of technology transfer is not only to commercialize academic IP but to also build the innovative capacities of PSIs, SMEs and entrepreneurs by facilitating collaborative ventures (Standing Committee on Industry, Science, and Technology 2017). TTOs are situated at the crossroads between innovative capacity, untapped economic potential and concerns for national security.

Advancing Regulatory Frameworks

Global Affairs Canada has the opportunity to make Canada's regulatory environment for the medtech sector significantly more efficient by facilitating the adoption of international best practices, demonstrating that Canada is a place where innovative products can thrive in an already competitive industry. By making it easier to access more international markets and by adopting international best practices, Canada can further demonstrate to investors and innovators that it is a hospitable environment for medical device innovators (Health and Biosciences 2018).

International regulatory cooperation has several benefits, especially greater economic and administrative efficiency (OECD 2021). A regulatory framework that recognizes other international standards will not only make it easier for Canadian medical device producers to expand their markets outside Canada, but will save the medtech sector hundreds of thousands of dollars and will have an even larger impact on new and start-up medtech companies (Health Canada 2019). Pooling intelligence with other regulatory partners will help alleviate backlogs from domestic regulators, helping the federal government reach greater administrative efficiency.

Recommendations

1. **The Trade Commissioner Service should create a knowledge mobilization hub that connects Canadian university R&D programs and Canadian post-secondary graduates with Canadian businesses that are active in Brazil, China, India, Israel and South Korea to share best practices.** These key markets are the focus of the Canadian International Innovation Program. As participating companies seek to develop new or improved products, services or processes and seek to collaborate on R&D projects with foreign partners, Canadian companies can seek the technical guidance of Canadian R&D programs. This university-industry partnership also presents an opportunity for Canadian university programs to learn how to better align their innovations with these key markets, which would eventually lead to easier commercialization and market integration.

2. **In collaboration with Innovation, Science and Economic Development Canada (ISED) and Health Canada, GAC should support in-licensing of domestic medtech devices by providing non-dilutive matching grants to Canadian firms that are willing to provide in-licensing. This will further develop innovation and minimize existing barriers that prevent the commercialization of Canadian medtech.** Through a cross-department investment and joint pilot project, funding could be drawn from multiple sources while allowing each party to have a stake in medtech development, resulting in an increased commitment to success. Funding could be equal or prorated based on budget capacity ensuring that costs are evenly shared. GAC and ISED should start by leveraging the existing Canadian TTOs to provide both verification and protection of IP, while sustainably fostering and driving world-class innovation into the global market. This strategy could complement and strategically feed into GAC's mandate of fostering innovation by creating a foundational starting point for Canadian innovation and expertise to be leveraged into both domestic and international markets.

3. **By working with Health Canada, GAC should promote procurement best practices that are both safe and economically sound by streamlining its procurement process and supporting the adoption of value-based procurement (VBP), which is already being used in countries with successful medical device sectors.** VBP is lengthier to regulate because it involves longer trial periods, but also assesses best value for health outcomes and increased quality of life (Medtech Canada 2021c). Over time, Canada's health sector can reduce costs by avoiding potential costly medical procedures. By adopting VBP, the approval process needs to be completed only once, saving time and money. GAC can facilitate partnerships between Health Canada and other international health agencies that recognize VBP assessments from other countries, which can expedite the approval process in Canada. While efforts are already being made through federally funded organizations such as CAN Health, local procurement is still a significant barrier to medtech companies. A coordinated approach to VBP can be an initiative led by the federal government.

4. **GAC should build on existing international partnerships and bilateral relations to expand the Medical Device Single Audit Program (MDSAP) membership to more countries.** Canada is already a member of the MDSAP, which allows for international cooperation in the medical device sector and is spearheaded by the Government of Canada. Currently, approval in Canada gives medical device companies access to only four markets outside of Canada: Australia, Brazil, Japan and the United States (British Standards Institution 2022). Other key economic partners that Canada should look to include are the European Union, China, India, Israel, Mexico and South Korea.

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References

Alin, Sara, Tiffany Fitzpatrick, Gregory P. Marchildon and Amélie Quesnel-Valée. 2022. "The Federal Government and Canada's COVID-19 responses: from 'were ready were prepared' 'to fires are burning." *Health Economics, Policy and Law* 17: 76-94. doi:10.1017/S1744133121000220.

British Standards Institution. 2022. "Medical device single audit program (MDSAP)." BSI Canada. https://www.bsigroup.com/en-CA/Medical-Devices/Our-services/Medical-Device-Single-Audit-Program-MDSAP/.

De Fuentes, Claudia, Jorge Niosi and Jahan Ara Peerally. 2020. "Exploring innovation and export interplay in Canadian firms." *Economics of Innovation and New Technology* 30(8): 786–806. https://doi.org/10.1080/10438599.2020.1786999.

Dooks, Daniel. 2021. "On the Cutting Edge: Canada is Where You Need to be for Medtech." *Invest in Canada*. https://www.investcanada.ca/blog/cutting-edge-canada-where-you-need-be-medtech.

EY Canada. 2020. *Pulse of the industry: Medical technology report 2020*. 8-20. https://assets.ey.com/content/dam/ey-sites/ey-com/en_gl/topics/health/ey-pulse-medical-technology-report.pdf.

Fraser, Neil. 2022. "Canada urgently needs to stop the brain drain and ramp up its health science manufacturing capability." *Toronto Star*, February 22.https://www.thestar.com/business/opinion/2022/01/22/canada-urgently-needs-to-stop-the-brain-drain-and-ramp-up-its-health-science-manufacturing-capability.html .

Government of Canada. 2019b. *Canada's Innovation Strengths and Priorities*. Trade Commissioner Service. www.tradecommissioner.gc.ca/innovators-innovateurs/strategies.aspx?lang=eng.

Government of Canada. 2019a. *Towards Canada's 2030 Agenda National Strategy*. Employment and Social Development Canada. www.canada.ca/en/employment-social-development/programs/agenda-2030/national-strategy.html#h2.04.

Government of Canada. 2020. *Intellectual Property Protection for Medical Device Companies in China*. Trade Commissioner Service. www.tradecommissioner.gc.ca/china-chine/market-facts-faits-sur-le-marche/0003688.aspx?lang=eng.

Government of Canada. 2021. *Economic-Based Threats to National Security*. Public Safety Canada. www.publicsafety.gc.ca/cnt/trnsprnc/brfng-mtrls/prlmntry-bndrs/20210625/07-en.aspx?wbdisable=true.

Government of Canada. 2022. *Plan your IP strategy*. Canadian Intellectual Property Office. https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr04622.html .

Health and Biosciences Table. 2018. *Report from Canada's Economic Strategy Tables: Health and Biosciences*. Innovation, Science and Economic Development Canada https://ised-isde.canada.ca/site/economic-strategy-tables/en/report-2018/report-canadas-economic-strategy-tables-health-and-biosciences

Health Canada. 2021. *Final Report: Fees for Drugs and Medical Devices*. Canada.ca. https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/fees-drugs-medical-devices.html

Hickey, Toni, William Barrow and Charles Harris. 2018. "The Pros and Cons of Licensing Technology." https://www.mayerbrown.com/-/media/files/perspectives-events/publications/2018/08/the-pros-and-cons-of-licensing-technology/files/the-pros-and-cons-of-licensing-technology/fileattachment/the-pros-and-cons-of-licensing-technology.pdf.

Kirkwood, Isabelle. 2019. "Procurement could be Canada's biggest barrier to commercializing healthtech innovation." *BetaKit*, May 7. https://betakit.com/procurement-could-be-canadas-biggest-barrier-to-commercializing-healthtech-innovation/.

Leo, Geoff. 2020. "Depleted national stockpile leaves Canada reliant on China for masks, gowns, and other supplies during pandemic." *CBC News*, May 6.https://www.cbc.ca/news/canada/saskatchewan/ppe-import-china-shortage-1.5552426#:~:text=CBC%20News%20Loaded-,Depleted%20national%20stockpile%20leaves%20Canada%20reliant%20on%20China%20for%20masks,personal%20protective%20equipment%20throughout%20Canada..

MacNeil, Maggie, Melissa Koch, Ayse Kuspinar, Don Juzwishin, Pascale Lehoux and Paul Stolee. 2019. "Enabling health technology innovation in Canada: Barriers and facilitators in policy and regulatory Processes." *Health Policy* 123(2): 203-214. https://doi.org/10.1016/j.healthpol.2018.09.018.

Marijan, Branka. 2021. "Crafting Canada's Techno-Diplomatic Strategy." *Project Ploughshares*, November 8. https://ploughshares.ca/2021/11/crafting-canadas-techno-diplomatic-strategy/.

Medtech Canada. 2021a. "Canadian Medical Technology Industry: Advancing Healthcare Through Innovative Technologies and Devices." https://medtechcanada.org/page/CanMedTech.

———. 2021b. *A Time for Change in Canada's Healthcare Supply Chain Strategy and Practices*. MedTech Canada White Paper, 1-6. https://cdn.ymaws.com/medtechcanada.org/resource/resmgr/Medtech_Canada_Supply_Chain_.pdf.

———. 2021c. "COVID-19 Product Pathways." https://medtechcanada.org/page/COVID-19ProductPathways.

———. 2022. *Addressing the Global Supply Chain and Shipping Crisis*.https://cdn.ymaws.com/medtechcanada.org/resource/resmgr/Medtech_Canada_Position_Pape.pdf .

NIBUSINESS. 2021. "How to Manage Your Patents." www.nibusinessinfo.co.uk/content/advantages-and-disadvantages-licensing-patents.

OECD. 2021. *International Regulatory Cooperation*. OECD Best Practice Principles for Regulatory Policy, 1-65. https://doi.org/10.1787/5b28b589-en.

OPTIMUS. 2017. *The Innovation Dilemma: Achieving Value, Health Outcomes and Contributing to the New Economy*. The Future of Medical Technology in Canada, 5-8. https://gallery.mailchimp.com/ee57ed699fe269d23646e430e/files/7c63e00e-8602-4d3c-88d5-6734fdf94aa0/MEDEC_Optimus_Research_Paper_Final.pdf.

Schaffer, David. 2022. "The Ins and Outs of In-Licensing." CT Innovations. https://ctinnovations.com/item/the-ins-and-outs-of-in-licensing/.

Shivakumar, Sujai. 2022. "Securing Intellectual Property for Innovation and National Security." Center for Strategic and International Studies, March 3. www.csis.org/analysis/securing-intellectual-property-innovation-and-national-security.

Snyder, Jesse. 2019. "How foreign companies use Canada's universities to steal away huge chunks of intellectual property." *Financial Post*, March 6. https://financialpost.com/technology/how-foreign-companies-use-canadas-universities-to-steal-away-huge-chunks-of-intellectual-property.

Standing Committee on Industry, Science, and Technology. 2017. *Intellectual Property and Technology Transfer: Promoting Best Practices.* House of Commons, 1st sess, 42nd Parliament. www.ourcommons.ca/Content/Committee/421/INDU/Reports/RP9261888/indurp08/indurp08-e.pdf.

Tulchinsky, Theodore H. and Elena A. Varavikova. 2014. "Health Technology, Quality, Law, and Ethics" in *The New Public Health*, third ed. 771-819. Academic Press. https://doi.org/10.1016/B978-0-12-415766-8.00015-X.

Two Labs. 2018. "The Basics of Licensing: In and Out, Drug & Facility." https://twolabs.com/the-basics-of-licensing-in-out-drug-facility/.

Universities Canada. 2017. *University intellectual property and technology transfer*. Ottawa, Canada: Universities Canada. https://www.univcan.ca/wp-content/uploads/2017/06/university-intellectual-property-and-technology-transfer-submission-june-2017accessible.pdf