January 24, 2020

Ms. Julia Douglas
Clerk
Standing Committee on Finance and Economic Affairs
Queen's Park, Whitney Block, Room B-304
Toronto, Ontario M7A 1A2
comm-financeaffairs@ola.org

RE: 2020 Pre-Budget Consultations

Dear Ms. Douglas:

Thank you for providing Edwards Lifesciences with the opportunity to submit our ideas for the 2020 Ontario Budget. Our submission focuses on improving patient care through access to innovative medical technologies for patients in Ontario. We recommend increasing the number of Transcatheter Aortic Valve Implantation (TAVI) funded procedures to meet patients' needs and the creation of a value-based procurement framework for innovative medical technologies as part of centralized supply chain.

Edwards Lifesciences

Edwards Lifesciences (Edwards) is the global leader in patient-focused medical innovations for structural heart disease, as well as critical care and surgical monitoring. Edwards was founded by Miles "Lowell" Edwards in 1958 and continues to lead the field of tissue replacement heart valves and repair products and advanced hemodynamic monitoring, which have helped treat and manage more than 2 million patients worldwide each year. Edwards supplies products and technologies to clinicians serving patients in over 100 countries around the world. Driven by a passion to help patients, the company collaborates with the world's leading clinicians and researchers to address unmet healthcare needs, working to improve patient outcomes and enhance lives.

Aortic Valve Disease

Age-related Structural Heart Disease (SHD) refers to acquired abnormalities or defects caused by wear and tear that weaken the heart's structure; its walls, valves and muscles. Heart valve disease is the most common type of structural heart disease. Heart valve disease occurs when one of the heart's valves no longer functions normally, affecting the heart's ability to pump blood to the body. Heart valve disease can be treated with repair and/or replacement of the valve. The most common type of valve disease is aortic stenosis (AS) which can be treated with Surgical Aortic Valve Replacement (SAVR) through open heart surgery where patients require prolonged hospital stays and rehabilitation or through TAVI, an

innovative, minimally invasive procedure where most patients can be discharged to their home within 48 hours.

Increased TAVI procedures

Recommendation: To increase the number of funded TAVI procedures in 2020/21.

Edwards applauds the work of the Minimally Invasive Structural Heart (MISH) Working Group and the collaboration of the Ministry of Health, CorHealth, and clinical subject matter experts who worked together to help inform and guide system planning for minimally invasive structural heart procedures.

Over the last four years, the number of TAVI volume allocations have steadily increased due to new compelling clinical evidence supporting TAVI as an effective therapy for severe AS patients. However, demand still outpaces funded procedures leading to months long wait times, often longer than the recommended wait time for many patients. The increased wait time has a 40 per cent risk of hospitalization and 5 percent risk of mortality. Edwards recognizes the Ministry of Health's increased funding for TAVI in 2019/20 but notes that wait lists continue to exist for patients whom TAVI is their best life-saving treatment option. For the 2020/21 fiscal year, Edwards recommends the Ministry of Health continue to increase the number of funded TAVI procedures, funding an additional 900 patients to meet current demand and improve wait lists.

As per the 2019 Canadian Cardiovascular Society Position Statement for Transcatheter Aortic Valve Implantation, it stated that TAVI is an important treatment option for patients with severe AS. Because of the recent changes and evolving indications for TAVI in the management paradigm of AS, the current focus should be on improving quality of care by increasing access to therapy, minimizing wait times, and measuring and reporting outcomes to provide optimal patient results. In the near future, Edwards would like to see the determination of AS treatment be a decision made by the multi-disciplinary Heart Team in collaboration with the patient in accordance to individual patient risk and other mitigating circumstances.

Value-Based Procurement

Recommendation: To create a value-based-procurement framework for innovative medical technologies as part of centralized supply chain.

Edwards recognizes that centralized supply chain and procurement is an opportunity for the Ontario Government to find savings and reinvest those savings in programs and services for its citizens. However, it is important to create a value-based procurement system for innovative medical technologies so that cost is not the only driver of decisions and price reflects the value they offer to patients and the healthcare system. Value-based procurement presents opportunities for savings and better outcomes. It would be a new approach for the Government of Ontario and one that was recommended in the report 'Advancing Healthcare in Ontario: Optimizing the Healthcare Supply Chain-A New Model'.

An effective value-based procurement system values innovation and breaks down traditional silos while considering life-cycle costs and sector-wide outcomes. It would establish a patient centered innovation framework and create a series of criteria and data points of evidence that will be considered during the analysis. The framework should be grounded in three guiding principles:

Principle #1 - Making explicit the value innovation: align metrics to science and outcomes.

The benefits of medical innovation are only realized if patients have access to those innovations. The Ontario Ministry of Health and Ontario Health can work collaboratively with the manufacturer to determine the evidence requirements for product uptake and ensure patient concerns are considered along with affordability. Industry can partner with the Ontario government to achieve access to medical devices in a sustainable manner without stifling innovation. Focus should shift to value not cost, and pricing should reflect value. Governments desire value for money. However, this should not be pursued at the cost of depriving patients of innovative medical technologies that could deliver value to them.

Principle #2 – Investing smarter: build capabilities for dynamic financial planning.

Ontario government's financial planning should be implemented to secure an open and collaborative priority setting in healthcare through transparent horizon scanning to identify potential new treatments and disease management innovations. The funding decision of new medical technologies should reflect the needs for better patients' outcomes, improved efficiency in diseases management and reduction of overall healthcare cost related to the patient journey. Through investing smarter, the government can foster an attractive environment for medical technology companies to make Ontario an early and key market for developing and launching their products.

Principle #3 – Adaptive path to medical technology innovation.

Prioritizing innovative medical technologies in life-threatening diseases and setting an adaptive path through the life-cycle of an innovative technology should follow a predictable path to attract further investments for the benefit of patients. The Ontario government can engage with industry partner to discuss opportunities for innovative contracting, coverage with evidence development and managed entry agreements and dedicated innovation funds to overcome the rigidity of the current purchasing systems in order to align health outcomes' measurement to the delivering of progressive innovation.

Establishing a value-based-procurement framework for transformative innovative medical technologies would streamline how the public sector buys health related goods and services. A robust value framework would consider five domains: (i) clinical effectiveness, (ii) patient outcome, (iii) operational efficiency, (iv) health system impact and (v) access to innovation. Each domain can be unpacked further to provide clear criteria. Clinical effectiveness would consider clinical outcome (including a comparison to standard of care and competitor products) and safety, including risk of adverse events that require more healthcare spending. Patient outcomes would consider speed of patient recovery and treatment burden like time in hospital and time in rehab, time to full recovery including pre- and post-procedure support and procedure quality. Resource savings, process improvements and infrastructure requirements would all be categorized under operational efficiency. The domain of access to innovation would consider procedure access, while the health system impact would consider appropriate care and societal benefit like improvement in citizen productivity and reduction of care burden on families.

In essence, a value-based procurement framework for healthcare would consider the total cost of a procedure, incorporating the technology and all costs associated with it such as length of stay, rehabilitation, readmission rates and impact of other associated costs.

It is essential that procurement of breakthrough therapies be done in an individual manner using value-based procurement instead of through large product portfolio procurement. This will give companies that produce innovative technologies a chance to compete for contracts beyond price which will lead to better outcomes for patients. In addition, for breakthrough medical technologies the clinical judgement for which product should be used should reside with the clinical experts and not solely with the procurement officers. It is important for the right therapy to be used for the right patient at the right time.

Conclusion

Edwards is proud of our contributions to the health of Ontario patients. We are pleased to provide recommendations for the 2020 Budget that will improve access to innovative medical technologies in Ontario and deliver value to patients and the healthcare system.

Sincerely,

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cc. Sharon Ryan, Managing Director, Edwards Lifesciences (Canada) Inc.