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Health Canada, Regulation and its Impact on Small Business

To whom it may concern,

Minogue Medical Inc. is a Canadian healthcare organization specializing in the delivery of innovative medical technologies, supplies and equipment to hospitals and medical clinics for over 33 years. Our mission is to act in partnership with healthcare professionals in the care, comfort and recovery of the patient by providing the highest quality medical products, personalized service and superior technical support. We are a company of knowledgeable, professionals constantly searching the world for the latest innovations and developments in technology to make health care more effective for our partners and more comfortable for your patients.

As a distributor of medical products from the US and Europe, timely regulatory approvals by Health Canada of new devices and equipment is of critical importance to our business. Based on our experience we hope the government would consider improving and streamlining regulatory policies to help not only grow business within the health care sector but provide Canadian patients quicker access to innovative technologies.

Despite having world class hospitals and research intuitions in Canada, the combination of our countries predominately publicly funded health care system (global budgets with a substantial amount of fundraising initiatives) and its relatively small population (<0.5% of the worlds population) result in Canada representing a small market for health technology. Many manufactures do not prioritize submitting innovative products to Health Canada and first focus on completing CE mark and FDA approval. To ensure Canadians have access to the latest technologies, its of critical important that we minimize barriers to entry and expedite Health Canada's approval process. If the innovative technologies are already approved and in clinical use in other developed countries, we should consider recognizing the foreign approvals and immediately approving them in Canada as do other countries that are non-FDA or CE.

Because of the current landscape in Canadian health care, medical devices are not often not available for use by Canadian doctors to treat their patients until several years after they have already been in use in other countries.

For example, the da Vinci Surgical Robotic system manufactured by Intuitive (US) has been in use globally since 2000 and in Canada since 2003. In 2014, the fourth generation da Vinci Xi system was approved in Europe and the US but did not become available in Canada until 2017. This negatively impacted our business as Canadian surgeons were exposed to the new technology at US conferences and their hospitals delayed purchase.

Capital medical equipment within Canada already has long purchase timelines considering the planning and fundraising required and adding any further delays is a real challenge for businesses. Furthermore, because of the unavailability of the latest technology some Canada hospitals choose to purchase older models which often have a shorter useable life. This negatively impacts the cost effectiveness since the amortization period is reduced due to potential product discontinuations.

The above Canadian regulatory challenges related to application, approval and availability also applies to new instruments and accessories and software updates. These complimentary products that often interface with already approved equipment require separate applications and amendments.

An example issue we experienced involves an advanced technology available globally for the da Vinci Robot. Intuitive did not submit to Health Canada approval for their wristed stapler product for the da Vinci Si system because the time and resources required to gain approval within Canada outweighed the potential sales within the country considering our relatively smaller install base and tight operating budgets.

This was truly unfortunate as this technology could have benefited many patients especially for rectal cancer surgery. Several surgeons from Canadian Hospitals still ask for access to this technology (now approximately 5 years old) and were even willing to complete special access paperwork.

Because of our country's lengthy application process and approval timelines for medical products, manufactures often group products including software updates into product batches. As a result, new software and product submissions maybe delayed by several iterations which often results in our technology being behind the rest of the globes users. This means that Canadian surgeons and patients do not benefit from incremental product and software improvements and often do not have access to latest clinically beneficial innovations despite global availability.

Canada is the only country who have made it mandatory to adopt MDSAP. This has discouraged many existing suppliers to no longer do business with Canada and many potential ones to avoid the Canadian System.

A radical change needs to happen at Health Canada. Because of the complicated and tortuously slow process, Canadian patients are not and, in some cases, will never get the best technology available to treat them and potentially save lives.

Sincerely,

Danny Minogue
Minogue Medical Inc.