

Interview: Jean-Philippe Gentès - President & CEO, Sterinova, Canada



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Jean-Philippe Gentès, President, and CEO of the rapidly growing ready-to-use injectable manufacturer Sterinova, shares his ideas on the 'Made in Canada' label, innovation in North America and the pros and cons of pricing pressures in healthcare.

Sterinova is a prime example of *Made in Canada* innovation, although Canadian innovation sometimes slips under the radar in North America. Are Canadians perhaps too humble to promote themselves on the international stage?

I think there is some truth in the statement that whatever fits in Canada's geography is always smaller and perhaps underestimated when compared to the United States. If we look at Sterinova, our market valuation in the US would be ten times the size of our Canadian operations. This is only natural though, when you compare any market to the biggest pharmaceutical market on the planet. Price regulation is far looser in the US, and the market here is more restrictive. The PMPRB (Patented Medicine Price Review Board) has been keeping prices relatively low in Canada, although the fragmented nature of the healthcare market and strong autonomy within each province combine to create a more challenging environment for pharma and innovative products seeking reimbursement.

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I often hear that Canadians are by nature, humbler than our American neighbors, and maybe modesty is in our DNA. Canada has an excellent brand image for pharmaceuticals, a strong reputation, and is well-regarded by Europeans and emerging markets alike. However, it suffers from scarce resources compared to American companies, and when it comes to setting a Canadian company up for launch outside of its home market, that can make a big difference. That said, there are many Canadian companies on the global market, although their number could be higher.

What more can be done to improve Canadian innovation and its competitiveness globally?

I think that government plays a critical role in growing the industry in the Canadian market and they need to continue their support. We have seen a lot of investment in big pharma companies, and far less in smaller players and start-ups. I would like to see more money channeled to the businesses that albeit smaller, stimulate innovation and create jobs that stay in Canada, as opposed to being sent to the classic MNCs in Ireland or Switzerland. We need to reserve more capital for our own-branded product, the *Made in Canada* product.

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In Canada, Canadian companies are sometimes sold too early, or Canadian projects are under-funded meaning we are unable to provide the platform for the great ideas that are conceived here. Canada lost several of its biotech companies in the 2008 crisis because of funding problems. While the country used to be at the forefront of biotech, and we were one of the top innovators in the biopharma industry, we have since fallen far down the list. With the government's support, and with assistance from Canadian financial organizations, I believe we can improve the situation.

A supportive government that invests in R&D, one that can support companies in their start-up stages, and one that shares funding in innovators and manufacturers such as Sterinova would improve Canadian innovation. It takes a lot of time and money to be successful. To start a company, you need significant amounts of capital for initial investment, for validation of facilities, and for unexpected costs and problems, delays are sure to promptly arise and surprise you. It takes time before a business becomes financially operational and sustainable, and produces at an efficient level.

How would you evaluate ease of doing business for a smaller company in Canada?

Doing business in Canada is relatively simple. The regulatory burden is similar to other countries, but the approval times are relatively short compare to others which represents a huge advantage.

As a fairly small market, the local players get to know quickly all the important stakeholders of the Canadian market.

What advantages are there to manufacturing in Canada?

Canada has a great reputation, and products made in Canada enjoy a strong brand in the international market. Canada is also part of the Mutual Recognition Agreement meaning that manufacturing in Canada opens the door to the EMEA market. Plus, we have access to Australia, New Zealand, and other top pharma countries. Our borders indicate the logical big step from Canada: to the US.

When you build a new facility like it was the case with Sterinova, you bear this proximity in mind, you need to think about expanding across borders, and the easy route for us is South. Thus, you want all of your facilities and products to comply with US regulations. It is easier for a Canadian company than say a business established in France or Italy, where the local market is France first, then EMEA—that is perhaps what makes the difference between the European and North American pharmaceutical geographies.

How does it benefit to be in the Saint-Hyacinthe Technopole here in Saint-Hyacinthe, Québec?

Having built our pharmaceutical plant here in Saint-Hyacinthe Technopole has turned out to be highly beneficial for us. Construction came off the back of a meeting with the former General Manager of the Saint-Hyacinthe Technopole, Mario de Tilly, who ambitiously and generously took on the project, despite the evident high cost. The Saint-Hyacinthe Technopole and indeed the city supported us wholeheartedly; without their help, the Sterinova project would not exist today. In Canada, there is a real desire to build and invest in brick and mortar.

Which unmet needs in the Canadian healthcare system are you addressing?

Sterinova brings ready-to-use injectable products to the Canadian market, intended for several purposes but primarily increasing dosage accuracy, and we practice standardization and workflow optimization. There is always a risk of human error in drug preparation, we want to eliminate this risk by reducing human interference in drug preparation. With ready-to-use products, as validated industrial equipment prepare the dose, it increases the level of accuracy and can help reducing the risk of misuse.

Drug standardization is also crucial in reducing medication errors, if doctors usually prescribe ten different doses of one product, and you present the market with three or four standard doses, it is

easier for medical practices to be standardized, and focus on what's commercially available. Again, in a standardized situation, if a healthcare professional moves from one center to another location, with such a straightforward level of standardization, there is less risk of medication error and safety is increased.

All our products are bar-coded, and they have a unique identifier code, which helps automating and improving healthcare workflows. Using ready-to-use products also saves time for nursing personnel. Saving time in healthcare is crucial nowadays—we often hear of workers' crises, understaffing, overworked staff, etc.—and our products partly remedy these problems. For example, ready-to-use bags free up more time because there is no more need for nurses or pharmacy technicians to prepare the bags; the same rule applies to our ready-to-use syringes.

Which markets are your products a good fit for?

Sterinova's specialty is providing ready-to-use products, which align well with prescribing habits of doctors, so any market that is close to Canadian prescribing habits is a good market. Canada and the US are quite similar so the US constitutes a logical choice for exporting; the Commonwealth countries also enjoy comparable practices. Our strategic plan is to think first about the Canadian market, while keeping a global outlook. The key to success is to think about not just the Canadian market but the entire planet.

What strategic developmental path have you laid out for Sterinova?

Canada is and will remain the essential market for Sterinova. Nonetheless, our international development plan will be key to the success of our company. If we want to grow faster, we need to look at entry into global markets.

Moreover, international market growth would reduce risk related to any domestic problems or government policy changes that could affect the pharmaceutical market. For example, recently Canada and its provinces have put a lot of pressure on pricing. Price decreases are a good thing for Canadian citizens as it reduces their financial burden, but unfortunately, it has knock-on effects for pharmaceutical companies, especially those with highly innovative portfolios. If we cannot reimburse innovative products, then at some point big pharma might decide not to launch their own products in the country.

The same applies to the generic industry; if there is too much price pressure, they are forced to reduce their margins and cut costs. Somewhere along the line, these cuts may affect the quality of the product. For me, it is nonsensical that we pay less for an ampoule of morphine than a bottle of

water! The product is sterile, made with high-quality materials, secure and regulated. It does not make sense that we pay so little for such crucial products, when revenues are to be reinvested into further development of product quality. With too much price pressure, the risk is manufacturers will shift their supply to Russia, Brazil, or India because those are markets where return on investment is more important. In the past ten years, Canada has seen an increase in drug shortages. We are standing on a double-edged sword: although price pressures save money for Canadian payers, it will reduce the long-term health access of Canadians to good and reliable drugs.

The key to success is innovation: bringing the drug to market in the most user-friendly format as possible. For example, switching from a vial or an ampoule to a bag or a prefilled syringe; for me, this is the way we should manufacture drugs today. Automation of medical practices and optimization of the process map for healthcare professionals are also essential.

What kind of partners are you looking for?

A partner who is present, interested and aligns with Sterinova's business model. Selling our products is not like selling any regular drug; you need to have an understanding of how best to sell the product and how to convince consumers that the price difference is worth the investment. The output of a bag machine is meager compared to a fully automatic ampoule machine; pre-filled syringes using a primary container are highly expensive compared to an ampoule or a vial. We have to continue convincing hospital clients and government that outcomes justify the small extra expense. We believe it is necessary because with each safer usage, the risk of medication error is reduced.

Establishing the right pipeline with the right partners to be able to optimize what is manufactured here is crucial. Over the coming years, we will invest more in R&D, especially in strengthening the development of a good product portfolio for both Canadian and international needs.

As an entrepreneur yourself, what piece of advice would you give to someone looking to start their own business here in Canada?

Everyone knows that starting a business is a tough venture. You should always allow for more time and more money than expected. You are going to face delays whether it be supplier or regulatory oriented. Being surrounded by the right people is just as crucial, and with a little bit of luck, you will do well.

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