Interview: Ã?ric Gervais â?? Executive Vice-President, Duchesnay, Canada

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Ã?ric Gervais, executive vice-president of Duchesnay Inc, a privately-held, specialty Canadian pharma company focusing on womenâ??s health, charts the companyâ??s successful growth over the past 25 years, the innovative portfolio of in-house and in-licensed products they offer, as well as their plans for international expansion.

Eric, you were Duchesnayâ??s first employee in 1992. What has kept you at Duchesnay for the past 25 years?

Duchesnay is a family-owned company, held by Groupe Pharmaceutique Boivin. Initially, the companyâ??s mandate was to develop safe and effective drugs specifically for use during pregnancy. This stemmed from when a member of the Boivin family experienced an issue during her pregnancy and there was a disagreement between the physician and the pharmacist on whether the needed treatment was safe for use in pregnant women. The decision on whether to take the drug was left up to her, which is a stressful situation for any pregnant patient. The Boivin family realized that there existed a significant lack of information on the safe use of pharmacotherapies during pregnancy, so they decided to focus on this area, not only by promoting safe pharmacotherapies but also by educating pharmacists and physicians on how to prescribe drugs during pregnancy â?? and not just our products, but any relevant product. Along the way, Duchesnay also built in-house R&D and expertise, and has also funded research chairs at the University of Montreal as well as the University of Toronto.

Growing the company has been a huge undertaking and my role has evolved dramatically from the beginning in 1992. Today, we have 270 employees across Canada and the US, all very attached to

the idea of helping pregnant women manage their health in this unique period of their lives. Maternal health is an area overlooked by the broader pharma industry because it is seen as a risky investment. R&D is costly, the returns on investment are not immediately obvious and the area is very dynamic. However, over the past 25 years, we feel we have been able to make a substantial contribution to the health and wellbeing of pregnant women both in Canada and globally. I even receive calls of thanks from patients that our products have helped and this brings an incredible feeling of satisfaction.

In terms of the industryâ??s lack of focus on womenâ??s health, would you say the market dynamics have improved in the past 25 years?

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In terms of maternal health, the answer is definitely no. At Duchesnay, we also in-license products and we have scoured the global market for companies looking for pharma companies that hold products for maternal health. We have seen a drug here and there for use in child delivery, but no one is really touching this patient population, aside from Duchesnay, and we are exporting our expertise in this area globally.

For the womenâ??s health market in general, my feeling is that the amount of money invested in R&D is actually decreasing. Specifically focusing on postmenopausal women, there has been a decline in the use of estrogen-based therapies to treat menopausal symptoms following the results of the Womenâ??s Health Initiative (WHI) clinical trials demonstrating potential health risks. As a result, the pharma industry as a whole shied away from this area of womenâ??s health and it remains an unmet medical need.

How is Duchesnayâ??s current portfolio split between in-house products and in-licensed products?

In the beginning, the vast majority of our portfolio was our own medications, but today, our portfolio is increasingly based on in-licensed products, all focused on womenâ??s health. As an example, we recently bought the North American rights for OsphenaÂ®, the only oral, non-hormonal prescription medication indicated for the treatment of moderate to severe dyspareunia.

A key realization over the past 25 years is that trying to in-license and bring new products into Canada is extremely difficult. Most international companies see Canada as part of North America and therefore look to secure a North American deal. As the US is ten times the size of Canada, often, the rights will be sold to an American company â?? who then do not commercialize the drug in Canada, for a number of reasons. For one, our entire country has a smaller population than the state of California. We also have a complicated regulatory system, there are ten provinces and three territories to contend with, and the country is bilingual. Many companies view this market as too much effort for too little return.

This problem is particularly acute in the area of rare diseases. About half of rare diseases drugs available in the USA and Europe are not available in Canada. Patients in need may be able to access them through special access programs but that is a very difficult process, and reimbursement is not guaranteed.

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This underserviced market lead Duchesnay to establish our sister company, Medunik, specializing in orphan drugs for rare diseases. Several years ago, we also established US affiliates of both our Duchesnay and Medunik companies. With a presence in the US, we can now offer a North American

deal to potential partners, giving them access to the populous US market, but also help ensure that important drugs are equally made available in Canada through our operations here.

The US is often seen as a very difficult market to break into because of its size and the competitiveness of the market. How did Duchesnay manage this?

It was certainly a learning experience. In some ways, the Canadian system is more closely linked to Europe because the healthcare system is more socialist. The US is a completely different market and sometimes, for a Canadian player, can seem like a different planet. What is critical is that you have to accept this difference, understand the system, and think differently â?? in order to work within it. While challenging, it is certainly feasible â?? and our success is testament to that. We now have four products on the US market. It is incredibly rare for a Canadian pharma company to successfully break into the US, so we are very proud of this.

There seems to be some changes occurring in the Canadian market access environment. How do you expect that to impact Duchesnayâ??s operations?

In terms of regulatory affairs, I would admit it is getting a little difficult for companies, but ultimately it is about how you deal with the environment. Attitude is very important. For us, we always try to keep the lines of communication with Health Canada open. For instance, when we bring in a new chemical entity (NCE), we do a pre-submission meeting with them to ensure that everything is on the right track. Health Canada is the market approval body but at the end of the day, it is the people within their walls that approve the drugs. If those people know the company they are dealing with and understand that it is not just a fly-by-night operation, the dynamics are different. What is important is that we focus on how we can work together and what Health Canada needs from us.

Very often, large companies see Canada as a small market, only 2 percent of the global market, and most focus on satisfying the regulatory requirements for the US and European Union markets, assuming that these efforts would also satisfy Health Canadaâ??s requirements. This is not the ideal approach. Sometimes Health Canada has additional concerns not required by the US or Europe, but it does not mean that these concerns are not valid.

In terms of market access, however, we are improving. Previously, because of the provinces and territories having their own processes, there were inequities in terms of patient access to products. This was especially the case with orphan drugs: a drug may be reimbursed in one province but not another, which does not make sense, because we are one country. Canadians should be able to access all drugs no matter where they live.

With more national harmonization like the pan-Canadian Pharmaceutical Alliance (pCPA) and the Common Drug Review (CDR) process, there is more consistency in market access. What does need to be improved is that pCPA increase the transparency and visibility of their negotiation process and potential outcomes to give an idea of how much they would be willing to pay for new drugs. Otherwise, it makes it very difficult for companies to build their business case for new products.

Duchesnay also manufactures in Canada. How does Duchesnay ensure the cost-effectiveness of its manufacturing operations here?

From a purely cost structure approach, companies would almost never manufacture pharmaceuticals in Canada. There are many countries where manufacturing costs will be considerably lower. However, when we consider the importance of our drugs and the vulnerable patient populations many are destined for, we decided to keep manufacturing in Canada so that we could have full control over the entire process. This allows us to maintain the strict quality and safety standards we are proud of.

The â??Made in Canadaâ?? label is also very attractive when it comes to exports. Our partners see it as a reassuring sign of quality. Our manufacturing plant is approved by Health Canada and FDA, and we are in the process of obtaining approval from the Japanese regulatory bodies. Our aim is to manufacture for the world from Canada.

Now that you have a strong presence in the US, what is your strategy for further internationalization?

Canada and the US are our core markets. We also already hold patents in about 42 countries and remain open to collaborating with partners. We are currently already represented in Singapore, South Korea and Israel.

We are looking to work with companies that take maternal health very seriously. We would like to build long-term relationships based on a foundation of trust.

As Duchesnay continues to expand internationally, how important will the Canadian market â?? as you said, only 2 percent of global â?? remain to Duchesnay?

It is not a matter of P&L. Canada is home for us. We are in the business of helping mothers and their children, as well as patients with rare diseases. In those cases, it is a matter of life and death. Canada is our home and Canadians are our family, so we will always be committed to the Canadian market.

Having built up Duchesnay, and recognized by the EY Entrepreneur of the Year award in 2013, would you say there is an entrepreneurial gene or is entrepreneurialism something that can be acquired?

Fundamentally, you have to like change and to have an appetite for risk. But beyond that, it is certainly something you can acquire. What is also important is to have a good mentor and mine was Pierre Boivin, owner of Duchesnay. It is important to be surrounded by the right kind of people, who will explain how the industry works. It is fine to make mistakes, but as I like to say, the first time is an error, the second time it is a mistake, and hopefully there is no third time!

The bar for entrepreneurship in the pharma industry is moving higher and higher because in order to start a pharma company today, you need more and more investment. But there will always be entrepreneurial families that will believe in their capabilities and build businesses that meet critical needs. I hope to see more of that in Canada in the future.

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