Interview: Patrick Nadeau – Vice-President (Business Development, Marketing and Operations), Lupin Pharma Canada

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Patrick Nadeau, vice-president (business development, marketing and operations) of Lupin Pharma Canada, highlights the journey of Lupin Pharma within Canada since its 2014 establishment, the strategic importance of the Canadian affiliate within its mission to become a global pharma company in both the branded and the generics spaces, as well as his priorities for the affiliate for the next few years.

Patrick, to begin with, Lupin came to Canada in 2014. What was the rationale behind the establishment of the Canadian affiliate then?

A huge motivating factor behind my decision to take the job was the fact that global management had a very clear vision of what they wanted from Lupin Canada. Lupin is recognized as one of the top five generics companies globally in terms of market capitalization, but Lupin also sees itself as a global pharmaceutical company and has an interest in developing a presence in the branded specialty pharma space. Since Canada is a top ten market, Lupin wanted to be present in this market as a matter of strategy.

This dovetailed nicely with Canada's market characteristics. The generics market is quite challenging in Canada; the industry has been growing in volume but declining in terms of value, so for a newcomer, entrance would have been rather difficult.

What has been the journey of Lupin Pharma in Canada so far?

I was in fact the first employee at Lupin Pharma Canada. The company had no presence here before so it was really a matter of starting from scratch. Together with the global management team, we built the strategy, decided what we wanted to do, implemented the plan, the various SOPs for things like obtaining a drug establishment license, documentation and so on, as well as selecting the products we wanted to bring to market. Understandably, it was a little nerve-wracking during the first few months. Nevertheless, three years on, we are quite happy with what we have accomplished, and personally, it has been a great learning experience.

The strategy was to explore the Canadian market. In many other countries, Lupin's entry point has been through acquisitions of local companies. In Canada, as in the US, it was a little different: we decided to start with a blank slate when designing and shaping the organization, making it both exciting and challenging. Whereas in the US, Lupin started from its internal products, in Canada, we first signed a licensing agreement with Salix Pharmaceuticals (before they were acquired by Valeant), with whom Lupin has had a global partnership. They had a few products approved in Canada but were facing issues with pricing and reimbursement, while we wanted to enter the Canadian market and had the local expertise to navigate the landscape here, so it was a great fit.

We have since also launched two of our own generics products. Our goal in Canada is to focus on branded specialty products as well as more complex and niche generics that face less competition and see greater medical need as a result of their complexity.

The company has not acquired any assets here. We do have an interest and capabilities to do so, should any interesting opportunities arise.

Canada is known to have a difficult market access landscape. How do you navigate that – as you contend with both branded and generics systems?

Canada has a very tough market access environment, especially in terms of reimbursement. It is a moving target, first of all, which can be a bit of a struggle. If someone tells you they understand the system completely, do let me know! However, the key to success is to bring value – that is Lupin's strategy in Canada and it has worked very well.

Looking at our products, they all bring significant value to the Canada healthcare system. Zaxine® received strong recommendations from both HTA agencies, the Canadian Agency for Drugs and Health Technologies (CADTH) and the Institut national d'excellence en santé et en services sociaux (INESSS) due to their significant value propositions. This really helps us navigate the market access systems. When you have a strong product, significant unmet medical need and clear pharmaco-economics, while it is not easy, the way is clearer.

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The same applies to generics. Our first generic is a single-source product and the second is a dual-source product, so these both generate significant savings for the governments.

Can you tell us more about Lupin's current portfolio in Canada?

The current split is around 70 percent brand and 30 percent generics. We have two branded products on the market: Zaxine® and InspiraChamber®. In 2018, we are planning to bring back to market the product Relistor®. While we have multiple generics products approved for Canada, we decided to be very selective and only two have been launched.

As a company, Lupin has one of the biggest pipelines in the world for a generics company. This is hugely exciting and in particular, we see many complex generics products within the biosimilars and inhalation space, so that is something we can look forward to in Canada as well.

On the branded side, we have built a sales structure in Canada to support that niche; for instance, we have recruited medical science liaisons (MSLs) as well as salesforce, and we are actively looking to launch more specialty products and new chemical entities (NCEs) within Canada.

How ready is the Canadian market for newer and more niche products like biosimilars and more complex generics?

There are already a few biosimilars on the market in Canada, which we see as a positive thing because there are challenges to being the first company to launch biosimilars or more niche products in a market. In addition to all the usual market access challenges and pricing pressures, companies also need to educate the market on the products. There is a promotion element that companies need to factor into their budgets. It can be difficult for payers to understand the value of the products within this space.

It is somewhat like the generics situations a few decades ago, when people were wondering if generics had the same quality, efficacy, and so on. Today, these questions have been more or less resolved for generics, but not yet for biosimilars.

The situation is similar for inhalation products because you have the active ingredient as well as the device, so you need to show interchangeability for both.

There are lots of learnings for industry, payers and physicians here – all the stakeholders. At the same time, because this area is more challenging, there are fewer players so we do see an opportunity here. We want to build the right company structure to pursue this opportunity, and we are committed to entering this space.

Indian drugmakers have seen a bit of a backlash in recent times due to regulatory issues. How has that affected the perception of companies like Lupin within Canada?

There may be a sort of stigma in general, but at the end of the day, industry insiders know and trust the quality of Lupin's products. Our facilities are inspected by international regulatory agencies like FDA and EMA, the sites are modern and frankly quite impressive, and we follow international manufacturing standards. India supplies a staggering amount of product to international markets. I think once people appreciate the size and full activities of the industry in India, they begin to change their preconceptions.

For instance, people may initially ask, 'Who is Lupin'? But once they find out that we are the fourth largest player in terms of volume in the US, and they see our facilities and company capabilities, they are invariably impressed. We do not want to hide the fact that we are an Indian company; we believe we bring huge value to the markets in which we operate. What is important is to communicate that clearly.

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For Lupin, the perception is that we always bring value to the market with our products. For instance, our main focus now is on Zaxine® (rifaximin), for which there was no alternative. It was given priority review of Health Canada because it was a real unmet medical need. The drug is for people with end-stage liver disease, who suffer from hepatic encephalopathy, where patients become easily confused and often have personality changes. With this pill, they almost 'come back to life' and become more functional members of society and less of a burden on caregivers as well. For this reason, it was termed 'the miracle pill'. Our focus has been on that, and the strength of this product gave the company a very positive image.

In terms of Lupin's overall footprint in Canada, what opportunities are there for Lupin to bring in R&D and manufacturing functions?

Currently, we have a commercial footprint composed of a marketing, medical, sales and distribution structure in Canada, with our salesforce mainly in the population centers of Quebec and Ontario, and a small team on the West Coast. We do some R&D and manufacturing in collaboration with other companies, government entities and universities.

Lupin’s manufacturing footprint is fairly well-entrenched with 18 manufacturing sites in India, United States, Japan, Mexico and Brazil. It is possible that through acquisition, we will build up our R&D and manufacturing presence here in the future; the balance sheet of the company is very strong so we do have the resources to invest accordingly, but for now we are pursuing a more partnership-based strategy.

Part of your role also includes advocating for Canada in terms of investment at HQ level. How do you stress the importance of Canada alongside giant markets like the US, Japan, China and even EMEA?

As I mentioned, the opportunities for Lupin Canada are in the specialty pharma space, not necessarily conventional generics. While Canada is a top ten market, in some specialty areas like inhalation, it could be within the top five in terms of size and market potential, and we have put in place a structure to commercialize branded products. For this reason, Lupin’s global management team is very supportive of the Canadian affiliate.

As the Canadian affiliate is one of the youngest within the Lupin organization, when we built it, we really focused on building an organization for the future. We like to see ourselves as the face of the future – where Lupin hopes to be better known as a global specialty pharma player. In this way, we can perhaps be a showcase example or a laboratory for best practices for other affiliates like the US.

On a more personal note, how has your previous experience with BMS and Pharmascience helped in your current role at Lupin Canada?

I believe this was my personal value proposition for Lupin Canada at that time. I have both branded and generics experience, as well as a background as a pharmacist. I also have an MBA, which means I understand the products as well as the finances of managing an affiliate.

Personally, I also really enjoy the variety of responsibilities that come with managing an affiliate. While it is no longer a one-man show, we are still a small affiliate and I am in the thick of the fray when it comes to all aspects of the business, from business development, pharmacovigilance, Health Canada audits and applications, sales and marketing, and so on.

Having been in the industry for nearly two decades now, what keeps you motivated?

Our goal is to grow Lupin Canada into a CAD 100 million business over the next five years. We have the passion and the team to deliver on that result, so it is all about execution of our strategy.

I personally love working in the industry because it is so dynamic and exciting; there are new challenges and opportunities all the time, and every day is so different, so it is easy to stay motivated. But ultimately, the beauty of the industry is in remembering the value that we bring to our patients. Our products really make a significant difference in people’s lives, whether because our branded products meet an unmet medical need or because our generics products are accessible to patients that previously could not afford treatment.

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