

Interview: Lyndal Walker – General Manager, Ipsen Canada



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Lyndal Walker of Ipsen Canada discusses the opportunities present in the Canadian pharma market for a mid-cap innovator like Ipsen, the value of Canada's research ecosystem, and emerging healthcare trends within the country.

Lyndal, you established Ipsen's Canadian affiliate in 2015. First and foremost, what opportunity did Ipsen globally see in the Canadian market at that time?

As a company, Ipsen does a lot of analytics and research to understand global market dynamics. Our products are present in 115 countries and we have established close to 40 affiliates around the world. Previously in Canada, Ipsen had an out-licensed product on the market. When we analyzed that product's performance and available market opportunities, in conjunction with Ipsen's upcoming pipeline, we decided that we had to establish a direct presence on the ground in Canada to build face-to-face relationships with healthcare stakeholders here – which is, after all, a top ten pharma market. We continue to have a licensing agreement with Galderma for our aesthetics franchise and now manage our core group of products directly.

In the past two years, we have achieved a number of milestones that I am very proud of. First and foremost, we obtained our drug establishment license, enabling us to import and sell pharmaceutical products. We have since taken back our out-licensed product, Somatuline® Autogel®, and also received approval for an additional indication for that product. Another product, Dysport Therapeutic TM, has also been approved, and we currently have seven submissions (for both new drug entities and new indications) pending approval by Health Canada. Furthermore, we have had reimbursement

success with two of our products, which is very heartening as the Canadian Agency for Drugs and Technologies in Health (CADTH) Common Drug Review (CDR) can be a difficult process.

Another priority has been to extend Ipsen's global in-licensing agreement for Cabozantinib from US-based Exelixis to Canada as we saw potential for the product in Canada as well. This was accomplished in December 2016, and this product has been placed under priority review by Health Canada so we expect patients to be able to benefit from this new product in an even shorter time frame. I would also like to point out that the active ingredient in this product is also fully manufactured and packaged in Canada to supply global markets, so it contributes to Canada medically and economically.

I would say Ipsen Canada has had a great start. We are somewhat of a poster child for the Ontario government now when it comes to attracting more foreign investment into the country, as our growth has been significant in the past two years. We have hired 50 people in two years and look to hire another 14 or so this year alone, in addition to tripling our office space.

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As a company, Ipsen has been shifting its focus from primary care to specialty care, with a few main products like Somatuline® Autogel® expected to drive company growth until 2020. What have been the main growth drivers of the Canadian affiliate to date?

Historically, Ipsen as a company has emphasized building external partnerships and out-licensing products but this has changed completely. We are now focused on the development, acquisition and commercialization of assets, which will ensure that we build a highly innovative pipeline. This is why One Ipsen is our lead for 2017 and 2018: we are transforming into one team, one Ipsen, focusing on face-to-face customer engagement, and bringing innovative products to help patients.

Somatuline® Autogel® has been hugely successful in Canada and in fact, we have had a higher growth curve than the US! We see patient benefit from administration to pharmaco-economics, so there has been a very positive uptake in the market. We expect this to continue, as well as for Dysport® Therapeutic™.

We have two upcoming product launches, both in-licensed products: Cabometyx® (cabozantinib) for renal cell carcinoma (RCC) as mentioned, under priority review now and telotristat etiprate for the treatment of carcinoid syndrome symptoms, which we plan to submit to Health Canada. Of course, as market authorization has not yet been obtained, the safety and efficacy of these products are still under investigation.

Looking forward, the five-year plan is to reach CAD 100 million in revenues.

Canada has a strong healthcare system, world-class researchers and physicians, and well-equipped medical and research facilities, so as a company focusing on innovation, how is Ipsen plugging into Canada's research ecosystem?

Ipsen sees significant value in Canada's research ecosystem and we have already invested in conducting clinical trials here, collaborating with leading Canadian key opinion leaders, research facilities and hospitals, and patient groups. We are also discussing potential projects with key universities like Queen's University, McMaster University and University of British Columbia (UBC). Furthermore, we have plans to place basic research in Quebec in the next few months, and aim to bring in phase II and III studies to Canada as well. This was a motivating factor behind establishing ourselves in Toronto as well, because it has the largest life sciences ecosystem in the country.

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Canada is at the crossroads of society â?? Toronto is the most diverse city in the world. We have the diverse demographics that any clinical trial would love to have. Canada also boasts a very robust ethics system and we lead the world in terms of promoting patient consent and transparency. As a further incentive, our currency is weaker than the American dollar, which is helpful given the huge expenditures associated with clinical trials.

I think Canada as a country needs to develop a better understanding of the research ecosystems available globally and continue to push the domestic ecosystem to greater heights. We have to compete globally when it comes to study placements because these are decisions made by Global Clinical teams, not the country manager. In terms of areas for improvement, one aspect is the lead time for study approvals, which can be one differentiating factor. Canadian stakeholders â?? from government entities to industry associations to business development groups as well as consultancies â?? also need to be stronger advocates of Canadaâ??s huge potential and advantages when it comes to pharmaceutical R&D. Canadian key opinion leaders have done amazing work and are held in the highest esteem globally, and we have world-class research facilities and technologies, but these facts are often not being fully communicated globally.

As an industry veteran, can you highlight some of Canadaâ??s healthcare needs and trends at the moment?

Canadaâ??s healthcare ecosystem is rather complex: it is a big country, it has a growing population and there are these different provincial and territorial systems that decide where funding goes. There is also an umbrella of national programs put in place but these do not all operate in a synergistic way. As a result, even when one aspect becomes more efficient, other elements in the entire chain may delay the impact of that efficiency from being felt. For instance, in recent changes to Canadaâ??s drug approval process, you can have priority review times being shortened but the funding models have not kept pace. Currently, one part of the funding process has agreed to pick up the file in 30 days but the oncology side has said they do not have the resources to achieve that, so the whole process still remains at the original 120 days. There is also an ongoing debate regarding drug pricing.

More broadly speaking, we also need to strengthen the overall life sciences ecosystem in Canada because we have excellent scientific discovery and development elements, but the commercial side of the equation can be constrained in terms of access and funding. The entire process can be made more fluid.

I have been in the industry for two decades now, so I have firsthand experience of different elements in the whole ecosystem. What is heartening is that various stakeholders are quite receptive to hearing feedback on how the system could be improve. As industry, we also have a role to play in advocating for the improvements that we believe need to be made. This means showing up with the facts on the ground so that all stakeholders involved are on the same page and understand what the issues are.

How would you like the Ipsen brand to be perceived within Canada?

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Fundamentally, we are a very patient-centric company. We treat people with life-threatening diseases and as a result, the voice of the patient in that process is very important. As a group, we have a dedicated Chief Patient Officer based in Paris, France, who is known worldwide and makes

visits to a number of key advocacy and patient support groups globally. Cynthia Schwalm, EVP and President of North American Commercial Operations, has a nursing background, so she is also a strong advocate on the importance of hearing the patient's voice. Locally, we also have patient advocates working with us in our clinical trials development.

I would say we are at the forefront of understanding the patient voice and journey, and stakeholders appreciate that we understand the interactions between patients and physicians, and how our products can become a vehicle that helps with disease management.

As an indication, thus far, we have assisted nearly 700 plus patients with access to our products through our IPSENCARES® program, a comprehensive patient support program, as well as drug reimbursement efforts. We have also been strongly engaged in philanthropic efforts through collaboration with patient advocacy groups here.

Fundamentally, I think as a company and industry we have to be ethical in terms of how we operate. Our reputation is very important to uphold. This impacts not only our work and interaction with patients and other healthcare stakeholders, but also when it comes to recruitment.

We have seen that some people are leaving the industry because of the negative public image that seems to be developing. This has been exacerbated by what I would perhaps call a maturation of the industry, with significant M&A activity going on in the past few years and major trends leading to many experienced personnel transitioning out of the industry. As an industry, we rely heavily on our people, who need to be highly skilled and experienced. How we find this talent and how we explain the industry to the public is critical, because there is huge value in the industry and the products that we bring to patients, but a huge amount of work goes into them and we need that talent pipeline as well.

As General Manager for Ipsen Canada, your role is also to represent Canada within the company. With Canada next to the largest pharma market and the US represents 24 percent of Ipsen's global sales and the industry's eyes on emerging markets like China, now the second-largest pharma market in the world, how do you advocate for Canada's at HQ level?

This is a very important element of my role. I worked it out very quickly that Canada needed to have a profile within the organization. I have been fortunate enough to have received strong executive support, firstly from North American President Cynthia Schwalm, and secondly, members of Ipsen's global executive team have also had direct experience of the Canadian market, most notably David Meek, our global CEO, who was previously the CEO and president of Novartis Canada, as well as Harout Semerjian, President, Specialty Care International & Global Franchises, who also previously worked at Novartis Canada affiliate early in his career. With them, a conversation about Canada therefore requires very little context.

When there needs to be context, it becomes a matter of providing the facts on the ground. Once you show the numbers, our growth aspiration and the impact we could have on the global business, people start to understand Canada's potential and we receive the support we need. Canada is often seen as a development market for general managers and rightly so, because of the complexity and size of the market. We have seen great successes in Canada as well as the US, and I believe there are lessons the North American growth model can share globally.

On a final note, starting up a business can be very difficult, but transitioning from a start-up company into an established organization can also be a challenge. How do you ensure that Ipsen Canada will make this shift smoothly and continue the growth momentum?

We are the new kid on the block but we have made a lot of noise in the past two years. As a matter of fact, our application to join Innovative Medicines Canada, the innovative pharma association, was recently approved, so we are pleased to receive this acknowledgement of our contribution to Canada's life sciences ecosystem.

Moving forward, success is a matter of focus and planning. Our focus is on understanding patient needs – we should not be distracted away from this fundamental element. As an organization grows, there is the risk that people become entrenched in the growing bureaucracy and stop looking externally on changes happening within the industry or the healthcare system. Canada can change dramatically, even if not necessarily quickly, but as an organization, we still need to be astute and responsive to any signals coming in in order to keep abreast of the latest developments. This also means maintaining relationships with stakeholders. Ipsen's corporate structure does support this focus as we work in business units, and there is a support structure that facilitates our work. This allows each of us to focus on our areas of responsibilities without losing sight of overall organization growth. I can confidently say that Ipsen Canada will continue its rapid pace of growth in the next few years!

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