

Interview: Ed Dybka, General Manager, Almirall Canada



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Tags: [Almirall](#), [market access](#), [R&D](#), [regulatory](#),

Having only arrived on the market last year, the GM of Almirall in Canada explains the company's regulatory struggles, the utilization of Almirall's global R&D infrastructure in Canada as well as the company's choice to enter the Canadian market and what products they are introducing into it.

You started Almirall Canada last year, having spent eight years at GSK as Vice President of Marketing and Sales. What were the initial hurdles that you had to overcome upon the creation of this new affiliate?

The first hurdle was to find and attract excellent talent. Educating the parent company on the pharmaceutical industry here in Canada and ensuring that they understand the dynamics of the Canadian market was another key task. Most importantly, establishing a vision and a blueprint for the future for the company for Canada was critical.

On a personal level, did you think there was any risk involved in making such a drastic change in your career?

I was Head of Marketing and Sales in GSK for 8 years and I had enjoyed a 24-year career there. Therefore, walking away from that and going to a company I had never heard of before was certainly a risk. I was giving up quite a bit in terms of equity, familiarity, and comfort. I knew nothing about Almirall, which could have resulted in a number of issues. The products and portfolio I was asked to take on might not be suitable for Canada, the company's culture could have been different from the one to which I was accustomed, and there was the possibility that I didn't work well with the people. Those are all factors that you can never quantify until you start a new position, even with due diligence. However, so far it has been a great experience joining Almirall.

What do you perceive to be the greatest challenges of the Canadian pharmaceutical market as it relates to Almirall's vision?

As it relates to Almirall's vision, the greatest challenge is the bureaucracy that is in place in Canada. The number of steps that have to be taken to bring a medicine to a patient in Canada is very daunting, especially for a new company like Almirall. Almirall is submitting the same information multiple times to different review bodies, which is a significant waste of time.

In that sense, could Almirall Canada act as a good lobbyist to the various stakeholders involved to ensure that Canadian patients get the drugs they need?

Almirall is a case study for any company in terms of what it assumed it would take to get a drug from concept to a patient in Canada compared to the time that it actually takes. When big companies have the necessary infrastructure along with a huge portfolio, products simply go into a machine and come out at the other end. These companies can absorb losses; for Almirall Canada, time is of the essence because it has no sales right now in Canada.

To what extent is Almirall Canada focused on research-based products in the Canadian market?

The affiliate's focus is on researched-based products and relies on Almirall's global R&D footprint and capability to bring new products to Canada. This affiliate will focus primarily on its respiratory and dermatology portfolios. Almirall is launching its new COPD medicine, Tudorza Genuair, this fall [2013]. Almirall has also obtained very positive Phase III data on the combination of Acridinium and Formoterol, which is the follow-on product to monotherapy. Almirall also has a LABA/ICS combo in the pipeline as well as a MABA. However, the unique aspect of its portfolio is that its Genuair inhaler is an excellent and differentiated inhalation device. It is already being recognised as the best inhaler in the marketplace and is the foundation for the future of Almirall in Canada.

The Canadian affiliate of Almirall was founded with a focus on respiratory and dermatology. Do these two specialty areas reflect the needs of patients across Canada?

Yes: COPD is a huge market but it is a huge medical need as well. COPD is the fourth leading disease-related cause of death. It is a growing therapeutic area, mainly due to smoking. In addition to that, COPD is the top reason for admissions to hospitals from emergency departments. It is a huge burden on the healthcare system and for patients, and it has slowly been recognized as a very important disease that needs to be managed better.

Canada is the seventh largest pharmaceutical market worldwide. Why did Almirall, an organization with presence in a number of countries worldwide, come so late to Canada?

Almirall started expanding first in Europe because it was close to headquarters in Spain. At that time, the priority was to expand geographically through Europe, where there is one regulator and similar healthcare systems. In Canada, the organization's business model had been previously based on partnering to license their R&D to other companies here because there were no operations in the country. Instead of giving away profits and control to a partner, Almirall felt it had enough critical mass in terms of business opportunity with their current portfolio to do it themselves. Almirall also came to Canada because it is the seventh biggest pharmaceutical market in the world as well as the fourth biggest respiratory pharmaceutical market in the world. Companies with a respiratory portfolio have to be in Canada because the country punches above

its weight in terms of size of market. Finally, Canada is very close to the United States. Almirall is partnered with Forest in the US, with whom Almirall is co-promoting a product here in Canada; this partnership gives Almirall more proximity to the American market.

How did this partnership come about and what were the mutual benefits for each organization? What advantages will this partnership bring?

Aclidinium, Almirall's core respiratory molecule was co-developed by Almirall and Forest, which is the origin of this partnership. Almirall has exclusive rights to the product in Europe and Forest in the US. Canada can act as a bridge between Europe and the US.

What is the potential for strategic partnerships with local companies through outsourcing or product in-licensing?

There are many big companies that partner with other companies today to commercialize, especially primary care products because the costs and risks to bring these products to market are really high. Almirall is open and looking for partnerships on a continual basis. Big pharmaceutical companies tend to want to have more control over their assets, whereas Almirall is more flexible in that way.

Net sales for Almirall in Q1 2013 were €170.3 million, a 14.9 percent decrease compared to the same period in 2012 due to reforms in Spain and generic competition. How will Almirall Canada deal with potential clashes from generic competition?

Because Almirall's portfolio is so respiratory-focused, it is more immune to generic competition than other therapeutics areas. Respiratory medication involves complex and technical inhalation devices, which are far more difficult to make generic copies of compared to a pill. Furthermore, the regulatory framework for generic inhalation medications or respiratory medications worldwide is not as clear or in some cases non-existent.

What advice would you give to people looking to start a business here in Canada?

I would tell them to make sure you hire people who know the local market. Almirall Canada has a couple of employees from Spain, which helps immensely. However, you need people who know the local market and empower them to operate with autonomy to address the needs of Canadian customers.

What are your goals for the next five years?

We want to create a company that has a highly engaged group of people and to ensure that the environment created for our employee base is attractive. From a business perspective, I hope that in five years Almirall will have several growing and important products on the market, and that it is recognized as a key player, if not a leader within the respiratory market in Canada.

Almirall is a great company with a great future. The organization has opened an affiliate in Canada, which is a great country and probably one of the best if not the best pharmaceutical markets in the world. This is a gem of a market, with transparency and a great health care system. We could use better patent protection, but overall it is a great pharmaceutical market.

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