

Interview: Ed Dybka - President and CEO, AstraZeneca Canada



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Ed Dybka, President of AstraZeneca Canada, highlights the successful 'return to growth' journey the affiliate has undergone in the past few years, his thoughts on the need for a renewed and modernized pharmaceutical framework agreement between industry and government, and the strong business case Canada needs to make in order to retain its vibrant life sciences R&D and innovation ecosystems.

Ed, you have an extensive background in the Canadian pharmaceutical industry. How does that inform your current role as President of AstraZeneca Canada?

As a Canadian that has worked in Canada's biopharmaceutical industry my entire career – spanning almost 30 years – I have an understanding of the history behind the industry.

Having begun my career with Glaxo Canada (later GlaxoSmithKline), I left in 2012 to establish the Almirall affiliate in Canada as employee number one! From an experience standpoint, heading-up a start-up means that you need to understand each and every aspect of the business, be it building a benefits plan for employees to obtaining an establishment license to sell drugs. I still have a picture of my first paystub, with my employee number '00001' right at the top! I learned a lot about the entire business, as well as the value of resilience from this start-up experience.

In 2014, AstraZeneca acquired Almirall's respiratory assets. As a result, I helped to close the Canadian Almirall affiliate and came over to head AstraZeneca Canada in the role of Country

President.

Globally, CEO Pascal Soriot has been leading AstraZeneca on a strategic return to growth. How is the Canadian affiliate contributing to this mission?

Canada has been on a similar journey to the rest of AstraZeneca – in fact, I would say we have been at the leading edge, because we were among the first affiliates hit by the patent cliff in 2012. We were among the largest pharma companies in Canada, largely due to blockbuster products like Crestor®, Nexium® and Seroquel®. In the span of a few short years, we lost half our Canadian revenues and dropped to the bottom of the top 10 biopharmaceutical companies in Canada. While a challenging time for the organization, hitting the patent cliff early has given us the opportunity to be one of the first affiliates to also bounce back, placing us now firmly on a return to growth trajectory.

Through Pascal Soriot's global leadership, AstraZeneca has a robust and exciting global pipeline that we can leverage at the local level. As a company, we have also made important strides to evolve our business and therapeutic focus to the three core therapeutic areas of respiratory, oncology, and cardiovascular-metabolic disease (CVMD).

As a result, we have been able to launch many new products, which has driven our growth in the past three years. This is critical because Canada has a very competitive generic environment; once a product goes off-patent in Canada, there is significant and rapid erosion of that business. With an exciting and ambitious launch agenda ahead of us, we certainly expect to continue growing for the foreseeable future.

Given the reliance on new product launches, how do you manage the market access challenges in Canada?

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That is probably the greatest challenge for us. I would characterize this as the most difficult pricing and reimbursement environment I have seen in 30 years. In 1993, Bill C-91 was passed by the Federal government to provide patent protection to industry – we had none prior to that – while in exchange, the industry agreed to having the price of pharmaceutical products regulated by PMPRB (Patented Medicine Prices Review Board) so that Canadians were guaranteed fair drug prices and a commitment by the industry to invest 10 percent of our revenues in Canadian R&D. This accord between industry, government and Canadian patients worked very well for the ensuing few decades, with the result that there was good performance across key indicators: market access,

pricing, R&D activity, and patient outcomes.

In the past five years, many elements of this foundation are being challenged, manifesting primarily in the increasing delays in market access timelines. Where it previously would take only months to get a product reimbursed, now we are looking at a time frame of up to two years. More regulatory and review hurdles have been created to restrict access, reduce prices or delay the introduction of new products, motivated chiefly by budget concerns; together they ultimately result in delayed patient access to new and innovative medicines. I would characterize the overall market access environment as rather chaotic and difficult to work in.

It is clear that the previous pharmaceutical framework now needs updating to better reflect advancements in research and medical innovations, support to ensure a thriving life sciences industry, and fundamental changes in our R&D environment and industry activity. Unfortunately, recent industry-stakeholder-government dialogue and collaboration on this have been minimal, which prevents a focus on developing a sustainable solution.

With such market access challenges and Canada representing only 2 percent of global industry sales, how important a market will Canada remain, for AstraZeneca but also more generally for the wider industry?

There is a very strong business case for Canada. Admittedly, the patient access and pricing environment used to be a strong pillar, and it is now being threatened. Nevertheless, there are a few other factors that a global company looks at when making a decision to invest in the Canadian environment. Firstly, we are a larger market than people frequently expect, and we are often forgotten because we are not the US, not part of the EU-5, or an emerging market with accelerated growth. However, we continue to be a top-ten market, and often compare favorably with markets that have much larger populations. The Canadian economy is also among the strongest within the G7.

There is also a robust and strong private sector representing roughly half of the Canadian market, which manages to provide access to new products fairly predictably and rapidly. Canadians tend to see drug coverage as a basic employment benefit, and companies are happy to provide this because we see the value of keeping our employees healthy, happy and at work. This contributes to the sustainability of the industry significantly.

Another strong point is the quality of Canadian scientific leadership, bolstered by a great R&D ecosystem. Canadian key opinion leaders (KOLs) are over-represented on the global stage. I am attending some of the largest European oncology and respiratory society meetings over the next

few weeks and Canadians will be profiled everywhere as keynote speakers and lead principal investigators (PIs) for large-scale global studies. Personally, I visit customers across the country and I see many specialists in small towns conducting world-class clinical trials. This makes me very proud to be a Canadian working in this industry! But I think true to stereotype, we may be a little too humble in not emphasizing this.

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On that note, part of AstraZeneca's new strategy is to achieve scientific leadership in your key therapeutic areas. How is the company leveraging on Canadian science?

Our R&D footprint in Canada has grown dramatically in the last several years, after a period of decline during the patent cliff. Since 2014, we have tripled the size of our Clinical Team from around 30-40 employees to more than 110 and growing. More notably, Canada has also been identified as a global hub for oncology, immuno-oncology and respiratory clinical trials. From our site in Mississauga, we are currently leading 27 global oncology/immuno-oncology trials and 10 global respiratory trials, some of these involving more than 30 countries around the world. This activity speaks volumes about the contributions of Canada within AstraZeneca's R&D milieu. Many Canadians are also lead Principal Investigators on global clinical trials initiated or sponsored by AstraZeneca. Canada punches well above its weight in terms of its presence on the global scientific stage.

In terms of our investment footprint, AstraZeneca spent CAD 84 million on R&D last year, proof that global sees Canada as an excellent place for R&D investment.

Correspondingly, I think Canadian governments could play a much bigger role, firstly in terms of appreciating the value of the existing life sciences ecosystem, and secondly, by investing to make this environment even bigger and better. I am presently the co-chair of Life Sciences Ontario and also sit on an expert committee advising the Ontario government on the creation of a provincial life sciences strategy, much like the one Quebec just announced in May. The Quebec government has laid out a very progressive plan, with finance, health, and economy, science and innovation ministries coming together to grow and promote the entire life sciences ecosystem in the province. We need more of such initiatives across the country.

Our industry needs to do a better job of communicating our industry's R&D footprint because there does not seem to be a general awareness of its strength and impact. Part of this has to do with the increasingly narrow and outdated way the federal government has defined R&D in Canada related to other comparable markets. While we invest CAD 84 million in R&D locally, the official Federal

finance figure may be half that because it does not include the whole scope of scientific activities we engage in, such as our increasing role in leading multinational clinical trials and new areas of science including Real World Evidence, Epidemiology, and Pharmaco-epidemiology. The way the industry conducts R&D today is significantly different than in 1991.

For instance, we have committed CAD 10 million to a new health sciences supercluster proposal from the government, which aims to use big data in health not only to create jobs, advance our economy and create brand new industries, but also to directly improve the lives of Canadian patients by providing better treatments and improved healthcare. This R&D commitment of CAD 10 million is not eligible for R&D credits or calculations.

What responsibility does the Canadian pharma industry have to communicate this entire discussion to policymakers and the wider public?

As an industry, we need to do a better job of sharing the facts and figures related to the industry's contributions.

Our biggest opportunity is to work with governments to create a stable and predictable pricing and reimbursement framework that ensures access to medicines for Canadians at fair and competitive prices. The risk is that Canada starts to pay the kind of prices seen in emerging markets when it is an affluent country with a first-class healthcare system. Canadians understandably want to be assured that they are not paying more than other comparable countries. Yet there has somehow been a perception created that Canadians are paying excessive prices on innovative new medicines, which is categorically not the case.

It is important to recognize that the development of innovative medicines is costly and has a high risk of failure. On average, it takes 12-15 years and costs roughly USD 2.6 billion to develop a new medicine, including the cost of failures. A growing understanding of the underlying genetic and biological factors causing diseases is creating an exciting new era in personalized medicine in which we can better target the right medicine to the right patient at the right dose the first time. With more targeted or personalized medicines, we are focusing on smaller patient populations and greater impact. However, the development cost of innovative medicines remains roughly the same regardless of the size of the population that will require the treatment – whether it is for 100 Canadian patients or 10,000. This is taken into account when pricing new medicines.

New innovative medicines are transforming care for patients fighting what were once considered fatal diseases like cancer, HIV/AIDS, hepatitis C, cardiovascular disease and more. For patients, new medicines offer fewer side effects, fewer hospitalizations, improved quality of life, increased

productivity, and importantly, extended lives. But considered holistically, overall spend on innovative drugs represent only 6.4 percent of total healthcare expenditure by Canadians. This percentage has not changed much in the past twenty years. These new innovative drugs are not overburdening the system to the extent that industry critics assume.

This discussion is very relevant for AstraZeneca because 2/3 of our portfolio is personalized medicine, meaning these are products where patients must have a corresponding biomarker. For instance, we launched Tagrisso®, a drug for lung cancer that targets a very small subset of lung cancer patients with the EGFR T790M mutation; similarly for Lynparza®, a drug for ovarian cancer. Personalized medicine is here to stay and in the future, there will be very few drugs prescribed without an associated biomarker.

On a more personal note, what has motivated you to stay within the Canadian pharmaceutical industry for your entire career?

“I am very proud to be an example of someone that has spent my entire career in Canada. It is an extremely collaborative industry and historically, partnerships – between all stakeholders and at all levels – have been very robust.”

The Canadian market is often seen as a stepping stone to global positions due to its size, sophistication and complexity. Nevertheless, I am very proud to be an example of someone that has spent my entire career in Canada. It is an extremely collaborative industry and historically, partnerships – between all stakeholders and at all levels – have been very robust. This means that the doors are always open. The market here is very dynamic and there are great opportunities to build a great career. I am definitely a testament to that as I began my career as a summer student in Glaxo’s warehouse packing boxes – three decades later, I am a President of AstraZeneca Canada.

This is a great industry that makes such important contributions to the health of Canadians, our healthcare system and our economy. Looking ahead, a personal goal of mine is to try and push the industry back on a strong footing so that the next generation can find the same sense of purpose and great opportunities in this industry as I did.

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