

# Interview: Ronnie Miller – President and CEO, Roche Canada

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13.11.2017

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*Ronnie Miller, President & CEO of Roche Canada, shares the lessons learnt over his 17 years heading the affiliate, the interesting dynamics and developments within the Canadian healthcare space, Roche’s significant R&D footprint in Canada, and his focus on developing Roche Canada’s multiple sclerosis, hemophilia and neuroscience portfolios over the next few years.*

**As a veteran of the Canadian pharma industry having headed Roche’s Canadian affiliate for 17 years now, how would you characterize the current moment in Canada’s healthcare and life sciences industry?**

Firstly, within the life sciences space, we are a great research country and we continue to conduct great research and science here. On the healthcare side, the industry is under tremendous pricing pressure from the government. Canada has a very complex pricing and reimbursement environment. The government approaches it from the perspective of price while the industry approaches it from the perspective of access. Finding that happy medium in between both sides is the current challenge.

In terms of demographics, Canada has an increasingly aging population much like most other developed countries. In general, 80 percent of individuals’ healthcare costs occur within the last 20 percent of their lives, so that is a key challenge for the healthcare system to face.

In addition to that, over the past 17 years, the industry has moved from a “one-size-fits-all” philosophy of drug treatment to a much more personalized approach involving biomarker-based

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diagnosis and significant differentiation within a single disease. To illustrate, where only one type of breast cancer was recognized a few decades ago, today there are 80 different types! This has been driven by an evolving understanding of genomics as well as developing computing and data analytics technology. We are witnessing the convergence of all these different ideas, and in many ways, there is an arms race across the world in the use and application of real world evidence (RWE) in healthcare systems.

Most notably, this has affected the industry when it comes to market approval. Today's market approval license applications do not just require safety and efficiency data but also increasingly ask for longitudinal data and track the results of that data over time. This will change the dynamics of both drug approval and drug reimbursement.

**Against such a changing backdrop, how should pharma companies adapt themselves to all these trends?**

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Companies certainly need to read the tea leaves. We are not an isolated industry and we cannot stay as ostriches with our heads buried in the sand. Every company needs to work more in partnership with other stakeholders and there is every opportunity to do so.

For instance, patients increasingly want to have more of a say in clinical trials. The near-instant availability of information on the Internet has empowered patients in their own healthcare journeys. In the HIV space, for instance, patients can be more informed on the latest technologies and therapies than some of their physicians. In the rare diseases space as well, sometimes we find that we are approaching patients to identify the right physicians for the conduct of clinical trials. Even patient recruitment for clinical trials, which used to be an onerous and expensive task, can now be done speedily and cost-efficiently through mobile applications.

Companies also need to be more flexible when it comes to pricing based on outcomes. For instance, a difficulty in oncology is that a drug may turn out to work for more indications than originally designed, impacting on overall healthcare costs. I can see the ecosystem move towards more personalized reimbursement, where companies are given a price as a starting point and subsequently, the price may change based on patient data.

**We have heard that there seems to be a rather adversarial relationship between the industry and governments in Canada. How much potential is there for the development of productive partnerships?**

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The environment certainly needs to change for the better. The crux of the issue, I suspect, is that as an industry, we inevitably deal with governments in segments. The health ministry sees us as a cost, the finance ministry sees us partly as a cost but also as a business opportunity, while the trade and industry ministry sees us an economic opportunity. I call this the holy trinity. If industry is to successfully communicate our full value to the government, we need to interact with these three actors at the same time to maintain a healthy equilibrium. This situation is complicated by the fact that the health ministry is sometimes not viewed favorably by other parts of the government as well, given that they are the largest spender of tax dollars!

In terms of the regulatory environment, as an industry, what we are looking for is really a degree of predictability, which has been somehow lacking in the present system. For instance, the pricing watchdog in Canada, the Patented Medicine Prices Reimbursement Board (PMPRB), seems to be

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developing a creeping mandate that increases pricing complexity for companies. We are also negotiating with the pan-Canadian Pricing Alliance (pCPA) on pricing but even after that, we have to finalize reimbursement with individual provinces. As reflected through the innovators' association, Innovative Medicines Canada (IMC), there is a need to drive better dialogue with the government on a less adversarial basis.

### **As a company, Roche is known to take a very partnership-based approach. How is Roche Canada leading the charge here?**

The Federal government recently announced a CAD 950 million 'Supercluster Initiative' and opened applications to interested parties. Roche has an initiative called CARE (Clinical Analytics and Real World Evidence) in collaboration with the University of Waterloo in Ontario and Princess Margaret Hospital in Toronto. For our 'Supercluster' application, we included other companies like AstraZeneca, GlaxoSmithKline (GSK) and Québec-based DalCor Pharmaceuticals, as well as tech giants like Amazon. The goal is to use RWE and data analytics to drive better clinical studies and treatment outcomes. We have raised CAD 200 million in cash and CAD 70 million in kind to support this initiative over the next five years. There were around a hundred applications on the shortlist and we expect to hear the final results before the end of the year.

Canada has the national ambition to shift its economy away from natural resources to innovation. Such initiatives will certainly act as an economic stimulant and benefit the entire innovation ecosystem.

Another great example is our work with Foundation Medicine in Boston, who probably has the biggest collection of tissue samples in North America, if not the world. This allows us to compare a sample taken from any patient to that database, which could suggest the three best recommended treatment to treat your cancer 'and not necessarily a Roche therapy, but whatever is most suitable. Alternatively, if I want to interrogate the database to identify 50 patients based on a certain set of criteria, that can be done very quickly. This could speed up patient recruitment for clinical studies, for instance. The challenge here surrounds patient confidentiality and privacy, which will take a great deal of discussion.

But in general, there is a great deal of potential in data analytics, and as a country, Canada is very well-placed to leverage on this. In fact, the Canadian healthcare system does not even know what it knows, so there is huge potential to mine all the data and bring insights to the forefront. The only way this will become possible is if industry, academics, government and other sectors like tech come together.

The advantage Roche has is that as a brand and as a company, we are seen as the company to speak to about personalized healthcare because we have promoted this concept for so many years now. Just as an example, Roche Canada has our own in-house RWE expert that participates on a number of such projects.

### **On that note, why has Roche decided to invest so significantly in Canada? What are the strengths of the Canadian R&D environment?**

There are a multitude of factors contributing to the strength of Canada's R&D environment. Canada is widely respected for the quality and consistency of its clinical trials, the English-speaking academic environment does help when it comes to the conduct of global clinical trials, and I am always immediately impressed by the number of Canadians sitting on and even chairing global advisory boards of pharma companies. We also have got a very heterogeneous society; we are very close to the US; and we have a robust publicly-funded healthcare system. All these factors coalesce to make Canada a very interesting investment location.

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Roche Canada punches well above our weight in terms of clinical studies; we conduct around 13.4 percent of global clinical trials in Canada on a sales base of perhaps 2.5 percent. This is hugely significant.

Outside of clinical trials, Roche also has a significant presence in Canada. This stemmed originally from Roche's historical presence in North America. The North American HQ was initially in New Jersey, but following the acquisition of Genentech, the New Jersey facility was moved to San Francisco – nine hours behind Basel, our global HQ. Toronto was right in the middle of both so many of the New Jersey jobs came to Toronto.

Following that shift, it was seen that Toronto has a great ecosystem for pharma. There were a significant university network producing qualified graduates, there was international flight connections and a great transport network, and the ability to conduct and oversee clinical trials all over the US. Many global positions could be filled in Toronto, so Roche Canada's footprint grew steadily. For instance, we have added Global Regulatory and Global Biostatistics functions, and more recently, 70 rather senior IT positions to build an IT Service Center for North America. What may surprise people is that Toronto is actually the fourth-largest city in North America, and larger than San Francisco!

### **As general manager, how do you advocate for the Canadian affiliate at the global level?**

You have to understand where you can excel. We are nimble, innovative and very unified across all the divisions here, even our Global Pharmaceutical Development (PD) facility. We call it a "One Roche" philosophy; the PD leaders sit on our leadership team, for instance. There is a lot of cross-fertilization and this "one-ness" is a big advantage.

I am also very proud that I have sent many Canadians into the global organization. They retain a strong connection to Canada and they are highly respected within the global environment. Canada is sometimes seen as the Switzerland of North America.

### **Looking more broadly, Roche's country of origin, Switzerland, has produced not one but two of the largest innovative pharma companies in the world with a population size that is a small fraction of Canada's population. Why has Canada not seen its own global innovative pharma company?**

Canada is certainly missing a homegrown global pharma company! I suspect that if Roche was Canadian, I would have a very different relationship with our governments. Looking at global pharma giants, I am sure their CEOs have close relationships with their respective country leaders. Nevertheless, I believe the train has left the station. The amount of investment required to take a scientific concept through the pipeline to global commercialization is almost prohibitive. These days, biotech companies simply have to work in partnership with big pharma companies.

On the bright side, however, the industry makes good partners. For Roche, we are very keen on investing in good technology being developed in Canada. For instance, Genentech has invested CAD 700 million in Xenon, a company in British Columbia focused on pain management.

To encourage more such investment, the government should be reevaluating its R&D tax credits policy. The current SR&ED (Scientific Research and Experimental Development Tax Incentive Program) system needs to be updated. For instance, clinical studies we conduct in Canada result in tax breaks but the investment industry places in biotech development is not. Supporting industry's investments in local companies through tax policy will certainly encourage more activity here. To be very frank, it seems that, like many other countries, Canada wants the innovation but it does not want to pay for it!

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## Looking forward, what are you most excited about for Roche Canada?

Our long-term future is to excel in the new areas we are launching into. As a company, we are expanding from our focus in cancer to include new therapeutic areas. The first is multiple sclerosis (MS), of particular relevance to Canada, because Canada has the highest prevalence of MS in the world, and it still is not clear why that is the case. There are also some world-class MS researchers in Canada. Furthermore, the majority of products on the market are for relapsing-remitting MS (RRMS) while we are negotiating a license application for the primary progressive indication, which is the most severe form. This will bring valuable outcomes for MS patients.

The second is hemophilia, where we have a monoclonal antibody product that will change the way hemophilia is approached in both the inhibitor and non-inhibitor patient populations. From the early patient evidence and studies, there have been some interesting and remarkable outcomes.

In the longer term, Roche would like to move back into neuroscience. There is also potential in infectious diseases, whose priority in the global industry has largely fallen in the past few years but with new developments, the ability to arm an antibody and specifically target or personalize the medicine for the patient is becoming increasingly sophisticated, and that will be the next stage for us.

I would like to see Roche Canada move more into those therapeutic areas as well as continue the professional development of my team here.

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