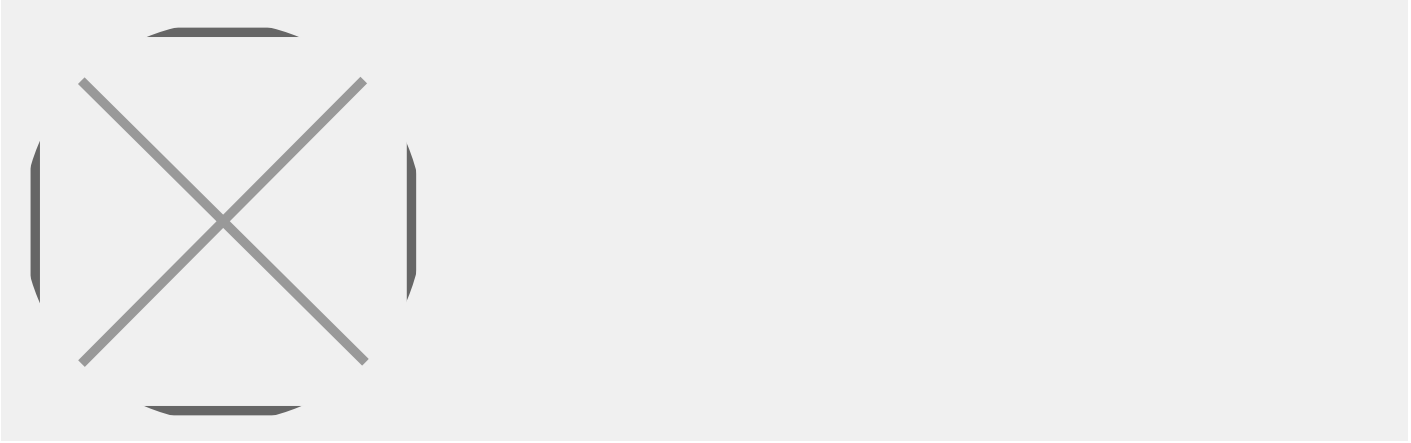
Interview with Russell Williams, President, Rx&D



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You have been President of Rx&D since 2004, and have witnessed the market's development over the years. What have been the most important issues since you started and what are you most proud of?

Our industry is developing partnerships with governments, universities, patient groups, biotechs to bring about the best research and development, and to talk about how we can work together to ensure the sustainability of our healthcare system. Rx&D partners with healthcare professionals and patient groups for better utilization of innovative medicine to improve health outcome for patients. Finally, research is not carried out in isolation; rather, it is an enormous effort on the part of all partners.

In terms of the issues on which Rx&D concentrates, one of the most significant issues is creating a solid environment for intellectual property (IP). There is a reasonable IP regime here, but to attract a better share of the CDN $120 billion worldwide investment, Canada needs the most competitive, harmonized and flexible IP regime to increase research. This is especially true given the fact that Canada has a relatively small pharmaceutical market (3 percent of global sales). It is also important to ensure that payers understand the value of medicines. A research-innovation strategy is obsolete and bad for healthcare if that innovation is not available to Canadians. Therefore, improving access to innovative medicines and becoming part of the healthcare solution is imperative. Most healthcare budgets comprise 35-45 percent of an entire provincial budget, and thus sustainability becomes paramount to reducing costs. I believe that Rx&D is part of a solution.

What are the primary challenges your members face today?

One of the primary challenges is ensuring that innovation is included in procurement strategies and is available to Canadians, given the restrictive nature of the economy. Rx&D can validate the long-term effectiveness of a medicine or vaccine. In terms of short-term budget difficulties, the biggest challenge is demonstrating the value of medicines as an investment versus an expense to the government and to private payers. Rx&D helps to bring innovative medicines to patients to improve health outcomes. Furthermore, the life science sector has the capacity to expand within the growing economy more than most sectors. In that sense, Canada is well-placed. Canada's healthcare system, databases, and infrastructure for research are quite well-grounded to attract a bigger portion of research dollars. Rx&D works to maintain the optimal balance. Rx&D is developing a much more partnership-focused business model. This could benefit every corner of Canada, from both a health and economics perspective. While the industry is focused on Toronto and Montreal to some degree, it will likely spread to wherever the best science and partnerships are. Given the issue of sustainability, the challenge then is to find the right partners to build what we call value-demonstrating projects, such as universities, small companies, research communities, and governments, to prove the value of medicines.

From 1990 to 2002, research and development (R&D) in Canada grew at a rate of 13.5 percent, leveling out at 0.2 percent between 2002 and 2006. How can Canada bring that level investment back to the level it was at 20 years ago?

It is the total environment that helps global head offices determine where investment will go. The first priority is to have great science and an infrastructure to support it, for which the government and Rx&D have created excellent investment opportunities. Canada does not have a complete package that allows for immediate commercialization, but this is improving. Secondly, Canada needs to have internationally competitive IP and an environment that supports innovation. It makes no sense to encourage R&D if you are not going to make it available for Canadians. Because innovative medicines and vaccines are often considered as a cost rather than an investment, the notion of accessibility of innovative medicines in Canada is also waning. I do not want to suggest that there is direct connection. However, Canada needs public policies that make innovation available to Canadians, which encourages research. Then, Canada will be well situated to grow quite quickly in research, particularly with clinical trials. While some barriers exist, Rx&D is part of a group that is working on issues such as the multiplicity of ethical review boards, template agreements, and recruitment retention issues. Those kinds of dollars are some of the most mobile

that Canada has, which would allow for great research. CDN $750 million of the CDN $1.2 billion investment in research is allotted for clinical trials, but that investment is decreasing. Addressing these issues will be great for patients, doctors, universities, and ultimately for Canada. Additionally, the Canadian healthcare system has some of the best databases in the world, which can be used to the country's advantage for further improving research opportunities.

R&D investments in 2010 in Québec were at about CDN $450 million, roughly 45 percent of all investments in Canada. What does Québec have to offer that makes it stand out?

Québec chose to strategically partner with the innovative pharmaceutical community 25-30 years ago through innovative public policy, which has made a tremendous difference. There are solid examples of Québec's public policy, such as tax credits, an active commitment to make innovation available, and its implications on provincial formularies, which make the province stand out. Québec is still a leader in rapidity and quantity of accessibility to innovative medicines. One particular policy, named BAP 15, guaranteed prices for a drug up to five years after the end of patent; although it did not guarantee exclusivity because provincial jurisdiction does not control IP. It was similar to the principles of a patent term restoration concept. This was a very strategic deliberate decision of the governments of Québec to encourage good healthcare and investment; at its peak, 50 percent of drugs in the province used this rule for price policy.

The commitment to life sciences and the strategic partnership with the innovative pharmaceutical community transcends partisan politics in Québec. All political parties have supported this endeavor over the years. This sometimes happens in other jurisdictions, but in Québec there has been a conscious decision to build a life science agenda, and it has paid off. Currently, the life sciences industry in Québec is changing its business and investment models; we are still spending CDN $450 million in the province but it is being spent differently. Rx&D is working with Québec to determine how the policies of twenty years ago can be as equally effective today. This is being done through a strategic alignment between the public and private sector, as well as an increased commitment to accessibility of approved innovative products for the people of Québec. In terms of economic commitment, the industry needs a return on the billions of dollars invested. Innovative medicines need to be available as quickly as possible, and that makes a huge difference.

You recently expressed dissatisfaction at the setting of the maximum payable price (MPP) for proton pump inhibitors, saying this would create more costs for the patient. What are the long-terms consequences of this, and is it a trend?

The notion of pricing is complicated. I am concerned by the decision of capping a price based solely on a fairly narrow discussion of cost and price of medications. It does not take into account the value and the total cost to the patient and the healthcare system. With proton pump inhibitors specifically, studies performed in Canada demonstrate that you may save money on the drug budget, but it will not give you as good health outcomes and it will cost you more in the overall healthcare budget. It is not in the best interest of patients. We believe that the healthcare professionals and their patients should be able to decide what is the best treatment, versus a decision based strictly on cost. It is an overly-simplified analysis of the cost and is not in anyone's interest.

It is incumbent upon all stakeholders, including Rx&D, to have a public, transparent conversation about this. In our industry, we have to continue showing the value of our medication.

What is your vision for Rx&D as an association? Are there any particular goals or reforms you wish to do?

Canada and other countries with public healthcare systems are experiencing intensive debates about sustainability. About 70 percent of healthcare in Canada is paid through a public system, while the other 30 percent is paid privately. My vision is that Rx&D can be part of the sustainability solution, and that the association contributes creative and interesting ideas, particularly with an ageing population. Looking at a curve or growth pattern for hospitalization, healthcare could suddenly become 50-70 percent of a provincial
budget. With disease and chronic care management and more community-based healthcare, Rx&D could become very much a part of a solution. The challenges faced right now are centered on becoming globally competitive in terms of IP. Europe and Canada are in the final stages of a free-trade discussion that would harmonize IP between the European Union and Canada. There is also a joint commitment to determine how to bring innovative products as quickly as possible to Canadians by targeting the right medicine to the right person at the right time. Looking at the Quebec model, Canadians had some of the most expensive generic drugs in the world for two decades. Now, governments are bringing down the prices of generic drugs. This is an interesting initiative because at the same time, those governments are committing some of those savings to being reinvested back into innovation.

I think that the failed public policy of Canada has been to overpay for generics. At the end of patents, there should be more competition and prices would be affected. Therefore, the payer (the state in this case), would have more money to invest in innovation. Yet prices remain high. Canada has a price ceiling for innovation and a price guarantee for generics. This sort of price control is an

unusual model.

Would you have a final message on behalf of Rx&D to the readers of Pharmaceutical Executive?

The primary challenge for Canada is to become internationally competitive on IP and regulation. If the country can have a policy and a healthcare system that supports and encourages innovation that is available to Canadians, I think that Canada will become a very exciting place to do research. Canada can show its capabilities to the world because of good research infrastructure through the country's universities and scientists. I am excited about the possibilities, and I hope that in a couple of years the industry will have harmonized. Canada has many exciting opportunities with its healthcare system, and the country has great scientists to do it. My board of directors is deeply committed to investing in Canada and developing techniques to improving the state of health here. Rx&D is spending a lot of time with various government agencies to develop the right models bring in more research dollars. The government has created many programs in good faith, but not aligned in the same way that is obvious to companies, and some of Rx&D's companies are not structured in a way that allows them to take advantage of those programs. It is in the interests of both the association and the government to increase such programs. Rx&D is tracking and coordinating some of those partnerships with the government, and thus I am very excited about the future.

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