Interview: Jim Keon – President, Canadian Generic Pharmaceutical Association (CGPA)



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Jim Keon, President of the CGPA, discusses how the Canadian generics industry is adapting to the current period of political transition and how it engages in talks with the government and other stakeholders to educate them about the costly and complex process of generic drug production.

Jim, we had the pleasure to meet you in 2013, where you discussed the generics industry's development in Canada over the last two decades as well as some of the key challenges and opportunities they were facing. How would you characterize the moment Canada is in terms of the generics and healthcare landscape?

In terms of the generics space, I think that we are in a transition period. Starting four or five years ago, when the Canadian provinces negotiated collectively through the pan-Canadian Pharmaceutical Alliance (pCPA), they have used their buying power to negotiate lower pricing. The reason why I refer to this period as a transition is because it impacts not only on our manufacturers directly, but also on the entire supply chain. In the generics market, there was a lot of discounting and rebating going on which ultimately impacted on pharmacies as well. It is requiring an alteration of the business model all around.

We will see more starting in April next year, as we have a one-year bridge agreement between the Canadian provinces. Going forward they are seeking aggressive price reductions. If we had not been able to negotiate a deal with the provinces, we might have had to go through a tendering

process, which is undesirable for a number of reasons. What all payers do now is compare prices around the world. Governments have their researchers pull up the pricing out of a tender model in Germany, the Netherlands or New Zealand and then they come to the conclusion that Canadian prices are higher than the average. There is an average price around the world that supports the development internationally that is much higher than a low tender price.

In the past, our products at retail level were higher than the international average. Part of what Québec is doing is reintroducing caps on rebates and the Minister of Health and Social Services of Québec Gaétan Barrette is going to cap it at 15 percent. He also passed legislation (Bill 92), which introduces some severe penalties for those who do not respect the regulations. The Health Insurance Board of Québec (Régie Assurance Médicaments du Québec, RAMQ) put out a communication on July 26 warning everyone in the supply chain that they would monitor and enforce these rules. Even if the other provinces do not put in the same restrictions on professional allowances, the impact on the supply chain is still going to occur simply because prices are going to come down. The entire pharmaceutical supply chain has had to adapt over the past five years and it will be the case for the next few years – probably in a more dramatic manner.

How have your members responded to this period of transition for the past years and are they ready for another round of more aggressive price cutting?

Yes, they are ready. We negotiate prices on behalf of our members and they are involved in the process. When we negotiated prices with Québec, the Executive Committee members were directly involved. The introduction of new products has currently slowed down, and this is why we are pleased with what Québec has done in response to recognizing the value of new products as part of its savings targets. Our companies are all international and these companies need to compete for resources to bring products to Canada.

While it is a small market, Canada ranks among the top ten for generics. While in Europe, you can get an approval for the entire market, as well as in the US, which is ten times our size, in Canada, it is very costly to bring products to the market. We have two major challenges from a regulatory perspective. Firstly, the increase of the regulatory scrutiny from Health Canada both for imported and domestic products, while maintaining a number of specific Canadian regulatory requirements which can require changes to the product or in the clinical testing. We have been challenging Health Canada to get rid of these – unless there is a strong and scientific reason why Canada should have a different rule than Europe or the US. Secondly, the provinces are driving the prices down, meaning that the margins are much smaller and it is more difficult than ever to bring products to the market.

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Do you think that the generics industry and the association are doing enough to communicate the different dimensions to the debate?

There are many elements to the pricing question. Many stakeholders are involved in the supply chain. This is true not only in terms of distribution but also at pharmacy level. Quebec Health Minister, Dr. Barrette, has talked a lot about this. He put a cap on professional allowance payments and he is going to enforce rules against other payments and excessive distribution payments. Ontario already has rules against that: you are not allowed to make professional allowance payments. The only thing that you are supposed to make is what they call in their legislation 'ordinary commission terms' and this is capped at eight percent, so presumably you can give a large customer a maximum of an eight percent discount. Whether this is strictly followed or not is difficult to determine.

Overall, I think the payers are aware of what was happening in the supply chain. They look internationally and they see our retail prices are relatively high, then they look internally and they see that there has been a lot of money going into the distribution industry. We would like to get to the point when we do not have to talk about prices all the time.

To what extent do you think this focus on pricing comes from the fact that the generics industry is not associated with innovation? We see from other markets that generics companies do invest R&D in their products but often this is not understood by policy makers. Is this the case in Canada?

I think this is true. The general public and the private payers do not understand the generic pharmaceutical business. Sometimes it seems as if they believe generic products grow on trees. We have tried to educate them on this matter by explaining that a lot of money goes into developing the active ingredient, doing the testing, developing the clinical trials and submitting it for regulatory approval. Furthermore, in Canada, we have to incur tremendous expenses in patent challenges because Health Canada can only approve a generic drug as long as the patent is cleared. This process is costly and perhaps we have not been very good at talking to our stakeholders about this. As an industry, we have talked about the impact that this lengthy process has on the generic market but until payers see drug shortages, they will not believe us. Because companies have been pruning their product portfolio by 20 percent, there is a concrete risk for future shortages.

Biosimilars was an exciting new area for CGPA in 2013, and CGPA established a Biosimilars board in 2015. What are the challenges there in terms of the slow uptake?

We have set up a sister organization called Biosimilars Canada. While it is part of CGPA, we have a separate board and we advocate separately about biosimilars as they are two different issues. The products are not necessarily bio-equivalent, so they are not interchangeable. The science is newer and the patient groups are less acclimatized to switching from biologic drugs to biosimilars, so the challenges are different. Biosimilars have been very slowly introduced into the Canadian market. The interesting thing about biosimilars is that you have quite a mix of companies, from traditional branded companies as well as generics companies.

Originator companies have had exclusive access to subscribers and patients and they have had the chance to build up relationships and people are not anxious to try newer biosimilars. Physicians have said that if a private insurance payer asked them to make the change to a biosimilar, they would, but they would not take the initiative themselves to have a patient switch to another product to save money. Until recently, Health Canada has also been conservative in the way it approached biosimilars. We have been pleased with the publishing of a new guidance on biosimilars that Health Canada released in December. They will be using a similar approach to the European Medicine Agency (EMA) allowing a more limited package of clinical trials in some cases.

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In terms of policy at the provincial level, while we have a generics price agreement with pCPA that biosimilars are specifically excluded from this deal, this means that each biosimilar sponsor will negotiate a price with the provinces in the same way originators do. The difference with biosimilars is that they are going to save provinces money, so the longer they delay, the less money they save. Another challenge is that originator companies have a public price but in addition they have also signed private pricing agreements with the provinces, which makes it difficult for Biosimilar companies to know exactly what the reimbursement price is.

Canada used to have a significant generics manufacturing presence. Has this changed a little bit over the past few years?

We still do have a significant manufacturing presence. Apotex, Teva, Sandoz, Pharmascience and Taro all have manufacturing operations in Canada to serve the Canadian market but they also export their products abroad. Companies like Apotex sell to over 100 countries. Currently it exports more to the US than it sells in Canada. While we have been able to maintain a strong manufacturing base it is an ongoing challenge with the low price products coming from India and

increasingly from China as well. I think Canadian manufacturers have been good at innovating and at reducing costs. From a quality perspective, there has been some backlash against the Indian products coming to Canada.

To begin wrapping up, as the voice of the Canadian generics industry, you mentioned that you are part of this international network of international Biosimilars. How should Canada be developing its positioning globally from a healthcare and life sciences perspective?

Despite all its challenges, the Canadian healthcare system is a strong one. Like many industries, it is constantly changing and evolving. When I started, the Canadian generic market was made up of small Canadian-owned companies. We had two large companies back then, Apotex and Novopharm (which subsequently was bought by Teva). Initially, they were more interested in protecting the Canadian market, but now everyone is interested in how to sell internationally and in particular how to enter the US market. Anything that could block our exports to the US could be devastating.

Speaking from a generic pharmaceutical space, we have been a leader for several decades, we have a strong regulatory system for generics through Health Canada. There is a strong international confidence towards the Canadian system. Often, we have dealt with issues that other markets have not experienced yet – so we have a lot of experience to bring. Through our IGBA group, we often have more influence than our size might indicate in terms of trade agreements or regulatory issues. I think we have a strong role to play.

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