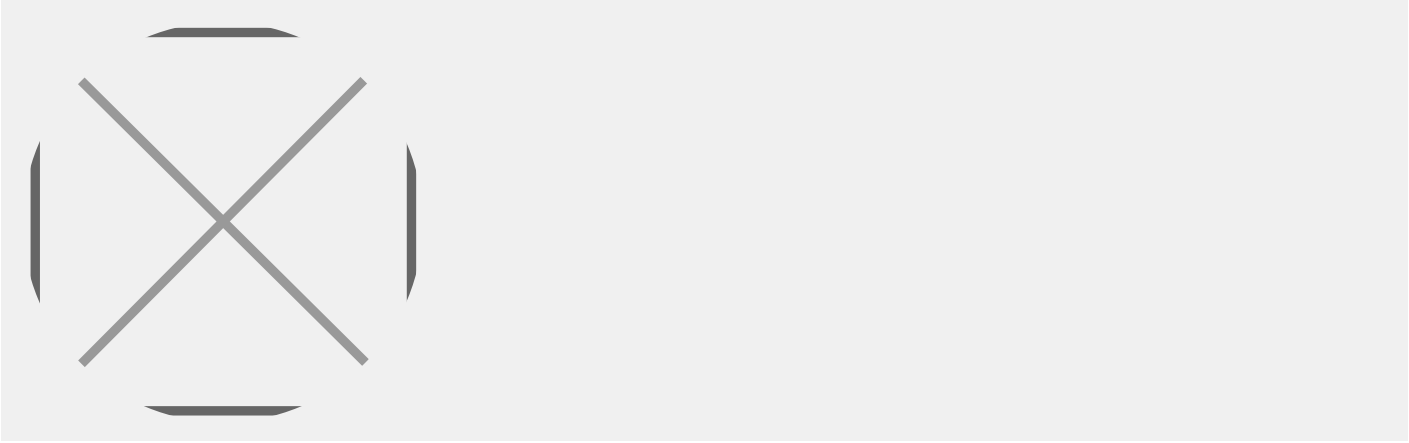
Interview: Jim Keon, President of Canadian Generic Pharmaceutical Association (CGPA)



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Jim Keon, Preisdent of CGPA, discusses the cost-saving benefits that generic drugs have offered Canada, and offers his insights into Canada's intellectual property regime and the challenges of pricing in Canada.

As a privileged witness to the evolution of the Canadian generic industry, what have been some of the defining moments of that evolution?

Twenty years ago, the generic industry was essentially owned by Canadian entrepreneurial pharmaceutical companies, which had grown out of legislation in Canada that had been progeneric. In the 1970s, the federal government introduced compulsory licensing of patents for pharmaceuticals. An entrepreneurial generic industry then grew to take advantage of that. The purpose of that legislation was to promote a pharmaceutical industry in Canada, which the country did not have at the time, and to bring down the cost of pharmaceuticals. From CGPA's perspective, that policy was effective but controversial and ultimately changed as a result of free trade agreements with the US and then with the World Trade Organization, in which Canada could no longer have separate systems of pharmaceuticals. By the 1990s, the Canadian industry was still essentially Canadian-owned. Companies like Apotex, Pharmascience, Technilab, Genpharm, Novopharm were all Canadian. Apart from Apotex and Pharmascience, all evolved into internationally owned companies.

I think the biggest evolution of the industry has been into the international scene. All of the major companies now operate worldwide and even those that are Canadian-owned have a worldwide vision. You can no longer be a successful domestically-focused company in Canada. The costs are too high, the litigation is too complicated, and you need access to the world market. Over the last five years there has been an emphasis on generic drug pricing, which has come down significantly. Ontario used to be the only province that had pricing rules, which employed the 70-90 rule. The first generic could not enter the Ontario formulary at any more than 70 percent of the brand name product, and the second generic could be no more than 90 percent of the 70 percent price (63 percent of the brand-name). At the time, most products were priced at 63 percent of their brand. That helped fund the generic industry, which was growing. However, as more generic companies came to Canada over time, the competition became more aggressive. Revenues, rather than flowing back to generic drug companies, were used to compete in the marketplace. The retail sector started to take more and more of the profits out of the system. A few years ago, a competition bureau report in Canada tried to determine why retail prices in Canada seemed to be higher than in other developed markets for generics, and found that the level of competition at the manufacturing base was actually quite high among companies like Apotex, Teva, Pharmascience, and Mylan. Because governments were regulating prices, retail prices were not sensitive to competition. A retailer would get reimbursed by the government at 63 percent but might have bought the product at a much lower price. This competition was occurring at the level of retail, and then those savings were not being passed on to the public or taxpayer through the government plan. The government started to reduce the price, firstly in Ontario to 50 percent of the brand-name price. Quebec uses the Best Available Price rule, which allows the province to generate savings based on Ontario’s decisions. CGPA thought that would be the new norm for a period of time, but over the last three years Ontario reduced its price further to 25 percent for most products, although this is negotiable. Quebec and Ontario make up about two-thirds of the market, and at that price. Over the last two years, almost every other province has introduced some form of price regulation as well.

Prices of generics are at 25 or 35 percent, and most have exceptions based on the characteristics of the product. These changes have been very difficult for the industry and especially for the pharmacy community, which had come to rely on those funds to grow their businesses. Often, when governments made price changes, it was the pharmacy community that complained the most, more than manufacturers, about the impact it would have. Canada is probably still not in a steady state. Last summer, provinces collaborated and announced that they would start tendering as ten provinces together for the largest-selling generic drugs. The generic industry opposed that;

it is short-sighted and would lead to problems in the future. The industry thought that there were better alternatives. CGPA had many discussions with provinces through this council, after which they changed their position. They stated that they did not want to start eliminating suppliers which could lead to concerns over drug shortages. They set the price of the top six generics at 18 percent of the brand name product, which was major. Over the last 3-5 years, the biggest change that we have seen is that the revenue base has declined. Complementing that, the demand has grown from cheaper prices. From a low of 40 percent, generic prescriptions now comprise over 64 percent.

It has been said that the failed public policy of Canada was caused by the overpaying for generics. While the price has come down in recent years, would you say that this has come too late in the history of Canadian generics? Why did it take legislation to bring these prices down?

The brand side is also regulated in Canada. The Patent Medicine Prices Review Board (PMPRB) is set within the Patent Act, which ensures that drugs are not excessively priced. The reality in Canada is that because of the heavy influence of the provinces in delivering healthcare and reimbursing medicines, provinces reimburse close to 50 percent of all medicines. Price therefore has to be regulated. Rx&D also fomented a lot of this issue to try to take the spotlight off their own prices and costs. The reality is that more than 75 percent of costs are still on brand-name medicines. Generic prices may have been high but three quarters of the cost were still on the other side. Generic prices are now much lower, and it is causing a restructuring of the industry.

Could you describe the country’s manufacturing capacity and expertise, given its creation of $34 billion in savings over the past five years?

The generic industry in Canada has been a success story. We have very successful companies. There is a bit of a cluster of manufacturing in the greater Toronto area and in Montreal to a degree. Apotex uses Canada as its base; it has plants in India, but it is essentially supplying the world from the Toronto facilities, which are massive. They sell the full range of products to the US, Canada and over 100 countries from here. Teva has several major facilities here for both domestic and international export markets. Pharmascience and Sandoz in Montreal also have significant plants. Canada is well served by the manufacturing capacity that it has with generics.

The ongoing trade talks are certainly a concern as well. Canada’s ability to be competitive internationally is excellent. The country has twenty year patents, data exclusivity of 8.5 years, longer than the US. Canada has complicated patent linkage regulations which have over the years led to a massive amount of costly litigation. If you are a pharmaceutical patent owner, you can put

patents on a list at Health Canada. When the generic wants to make the product, Health Canada cannot give you approval until you demonstrate that you will either wait until the patent expires or you will challenge some of them as being either invalid or that you are not infringing. If you simply wait, you will never come on the market because you do not have approval. Companies spend a great deal of time and effort looking at patents, and determining if they can make a product without infringing and then spending that money to come to market. Companies rarely challenge basic chemical compounds, they wait for it to expire and then they will challenge subsidiary patents around new formulations or indications to see if they can bring the product to market. That is very costly. The net effect of 20-year patents, data exclusivity, and litigation is that generic products enter the market in Canada approximately the same time as in the US and Europe. For a brand-name company, what matters is the period of exclusivity. Canada is very close to the US/EU average, which is roughly 13 years.

How do you serve as an advocate for strengthening IP protection in Canada, and what is CGPA's role in that?

CGPA does not want to see further strengthened IP protection in Canada. In most cases, a generic cannot enter the market until IP protection has run out. I would dispute the comment that Canada lacks in IP protection. That is clearly what the brand-name industry is advocating. Canada has been negotiating with Europe for four years and still has not reached a consensus. One of the major issues at stake is whether Canada should have longer patent protection. European negotiators have listened to their own companies and have aligned on export and business interests in Canada. Essentially, longer protection in Canada would be good for companies in Europe. Europeans have tried to convince the Canadian government to introduce patent extensions and longer data exclusivity. Furthermore, Canada has patent linkage, which Europe does not. In Europe, the competition authorities have said that it is anti-competitive, and that it blocks a generic before it has an opportunity to challenge patents. There is an automatic block. If you look at actual exclusivity in Canada versus Europe, there is a full complement of Canadian protection with 8.5 years of data exclusivity, patent linkage system, 20 year patents, evergreening patents, multiple patents available, a very good system at Health Canada, and prices are set by the PMPRB to be non-excessive compared to the seven highest-priced countries in the world. All of that together gives you a strong level of protection in Canada. In many cases the business environment for brand-name pharmaceuticals in Canada is much better than in Europe, where prices are low and IP protection does not last as long. Brand companies make a lot of money in Canada.

Where does Canada fit in the world of international drug production, and how will the upcoming Trans-Pacific Partnership (TPP) talks affect this?

Canada is a small but important player in the international generic pharmaceutical industry. In terms of amounts of production, Canada is behind the US or Europe, but has been a very important player for many years. Regarding CETA, if the European proposals are accepted, it could take 3.5 years longer for a new generic to enter the Canadian market. As an industry, if we are delayed 3.5 years before we can make new generic products, they will not be made in Canada. They will go to India, Brazil or the US when the patents expire. You will not wait 3.5 years and then try to make and sell a product in Canada. That is our biggest concern as an industry. The introduction of generics is very time-sensitive. You have to be ready to go on the market. If Canada's patents are longer than elsewhere, the industry will be put at a disadvantage if these proposals regarding data exclusivity end up in a trade agreement. Generics will become a rust-bucket industry. Canada will continue to export the products it already makes, but moving forward the country will not get new investments for new, specialized and difficult products that are desired.

CGPA is following the TPP carefully as are our counterparts in the US, the Generic Pharmaceutical Association (GPhA). One area of concern to CGPA would be data exclusivity, in which the US is promoting their twelve years of protection, which keeps you off the market for a long time regardless of patents. I would not like to see that move forward. The political dynamics of TPP are of course totally different compared to CETA. Canada and Europe are developed regions, whereas the TPP is a real mix of big and small, developed and developing. I am not sure how it will turn out. I do not want to see two-tier requirements based on a country's economic prowess. As an industry, this is undesired. The industry wants to be competitive in attracting ongoing investment. Furthermore, the timelines that government leaders are proposing for TPP are completely unrealistic, considering Japan has not even formally entered yet.

What are the biggest challenges your members face today?

Pricing is of course a big challenge. There is much lower revenue going forward compared to five years ago. Many products developed over the last 2-3 years that are coming out soon would have been started with a certain price level in mind, which is no longer the case. On the domestic market, Canada is mature for generics. Volume is growing. Canada has approximately 65 percent of all prescriptions filled with generics, and I would like to see it at 80 percent like it is in the US. With the current gap in prices, it makes more sense. The industry has been working more with private payers as well as insurance companies and pharmacy benefit managers to ensure their plans are generic-friendly and provide savings. The overall level of competition in the market is a

challenge. Canada is also seeing an increasing entry of small companies bringing in a few products and obtaining registrations. Many of these are Indian companies with brokers or agents in Canada who register their products and then find niche customers. That seems to be a growing phenomenon, and fully-fledged pharmaceutical companies like Apotex may find it very difficult to compete on price with some of these very small companies.

To what extent is the blurred line between generic and innovative companies reflected in the association's membership structure, strategy and evolution? Has it re-defined the role of CGPA?

Not yet; but it is something that CGPA is very aware of. Sandoz is the classic example: owned by Novartis yet has a separate generic entity. The views of Sandoz on trade policy and IP might be slightly different from Apotex, a fully-fledged independent generic company. Teva has stated that it wants to evolve into more of a mixed company, focusing on niche and innovative products, looking for new formulations, and different means of providing products. Worldwide, especially in the developed markets, generic products are seen as commodities. It is very difficult to make a business case for this going forward. Many generic companies are trying to move away from just supplying commodity products because it is not a recipe for going forward. How do companies make money? The US has a six-month exclusivity that everyone tries to obtain to be successful. You can make money on litigation and patent settlements, which can still be pro-competitive. There is some money to be made in niche products like injectables from a business perspective. Companies need to have broad-based commodity products to offer to their customers to run their plants. However, they also need to have some other way of separating themselves from everyone else to try to make extra revenues. All of CGPA's companies are doing that, and I would agree that the lines are sometimes blurred. For example, Pfizer talks about being a mixed company today with generic businesses around the world. The difference between Pfizer and Sandoz and Teva is not as clear as it once was. I think that as a trade association, CGPA still represents the generic business, which is indeed evolving.

Where do you see the CGPA in five years, and what are your personal objectives?

I think one of the new areas that might be exciting for Canada is biosimilars. There are no biosimilars at the moment, but Health Canada has provided some guidelines. Essentially, biosimilars will still be considered on a case-by-case basis, which has been very slow in Canada. Uncertainty around patent issues has also caused some slowdown, and some old patents are affecting the availability of products in Canada. I would think that Teva, Apotex, Mylan and others are all hoping to bring significant number of biopharmaceutical products to the Canadian market.

That would be one new area. Beyond that, it is hard to say. It will be interesting to see how some Canadian-owned companies evolve, whether they continue to be Canadian-owned or become part of larger global corporation. Volume-wise, growth potential in Canada is good. The country has an ageing population and healthy economy, and will still be a good market, but I do not see price pressures going away either. That is why companies will have to move into new types of products whether they are biosimilars or new formulations or in some cases their own innovative products. Apotex owns 80 percent of the largest biotechnology company in Canada, Cangene. All of our companies would to some extent see themselves evolving into a bit of a mixed company. In five years, I expect that to be more pronounced than it is today.

What does the international community need to know about Canadian industry?

From the Canadian perspective, so many of our issues now are international issues. One of the areas that our industry wants is harmonization on the science and regulatory side. More and more of Canada is part of an international situation and whether it is for science and regulatory approvals or patent laws, we need to fit in, try to do what is best for us while being part of global companies, part of a global regulatory system. Health Canada is active there, but we would ask them to be even more enthusiastic of those efforts. The days of being an island are over.

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