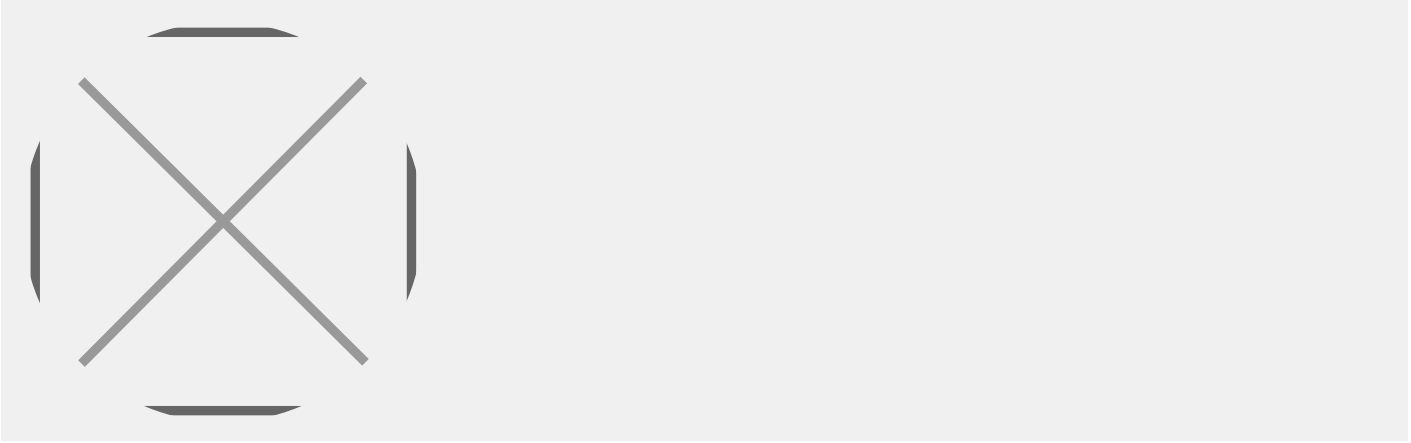
Interview: Andrew Casey, CEO, BIOTECanada



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BIOTECanada is the national trade association for Canada's biotech industry. Andrew Casey, the group's CEO, discusses the impact of IP regulation on emerging biotech companies, incentives for developing the sector on a national level, and offers perspectives on tax policy and its impact on drug development.

How does BIOTECanada actively participate in ensuring a competitive IP regime in Canada?

Canada competes in the global economy. In this context, we must stay competitive with other countries also home to, or looking to attract, successful biotech industries. By way of example, the show floor at the recent BIO in Chicago was dominated by countries, regions and states all looking to attract biotech companies to their jurisdictions. Canada's competitors recognize the enormous economic and social potential the biotech industry represents and are correspondingly taking steps to attract capital investment and encourage biotech research and innovation. Putting in place a strong and competitive intellectual property regime is a cornerstone to establishing an innovation culture – it sends positive signals to investors and innovators as they think about where to deploy their capital or develop their ideas. Capital and intellectual property are like a fussy tourist; they will go wherever they feel most welcome. To attract capital investment, countries must emulate a hotel and how it attracts guests: they need to offer incentives. Competitive IP regimes, tax policy, streamlined regulatory systems are the public policy equivalents of free wi-fi, free breakfast and rewards programs. If one country has great IP protection, others must keep pace. Ideas and capital

are very mobile- they will ultimately go where they will get the best return on the investment. IP protection along with other ‘hosting conditions’ that help to nurture an industry determine where innovation and capital will flow. In this context, it is absolutely imperative that Canada keeps pace.

BIOTECanada’s membership is representative of the diverse industry ecosystem in Canada. And while the association has a number of large companies, the smaller domestic companies have just as big of an interest in having their IP protected. That voice is an important one to bring to the table to demonstrate to the Canadian government there are numerous players large and small, domestic and multinational. There is an integrated ecosystem at work here, one where big companies are partnering with smaller ones for research and pipeline development. Policymakers must understand the interconnectivity of these varying interests. Helping government to see the importance of a strong and competitive IP regime in this context is certainly a role for BIOTECanada to play.

Canadian law grants 20 years of patent protection to companies that develop new drugs, a window of time designed to allow breakthrough developers to see a fair commercial return on investment. Yet many Canadian players lose more than half of that window due to issues like complex regulation, human resource issues, or supply chain problems. How might changes in patent law help speed up the process?

Patient safety and therapeutic efficacy are paramount objectives for both the industry and governments. A rigorous and effective regulatory approval and oversight system is essential to ensuring treatments are being developed safely and work effectively for patients. There is general agreement in the industry that Canada’s regulatory system is very good and in some respects a competitive advantage for the industry vis-a-vis other jurisdictions. Indeed, other countries often look to Canada as a model for regulatory oversight of the industry. That said, medicines and their development are complex undertakings. New technologies have resulted in rapid and significant advancements in healthcare therapies, particularly in the realm of biologic medicines. Moreover, biologic medicines themselves are vastly more complex than traditional small molecule medicines. Not surprisingly, given the pace and extent of change in the industry, there are parts of Canada’s regulatory system in need of modernization. In this context, BIOTECanada is working closely with the government of Canada to modernize and streamline Canada’s regulatory system, which will ultimately improve access to medicines and therapies for Canadians. The development of a national orphan drug strategy is an excellent example of government and industry identifying a challenge and working together to develop forward looking public policy that will deliver healthcare solutions for Canadian patients, and others globally, who are suffering from rare diseases.

What is your assessment of the ways in which drugs are priced in Canada?

The industry is very aware governments everywhere are under extreme financial pressure and are correspondingly looking for ways to reduce costs. With aging demographics, healthcare budgets tend to be one of the more significant costs for many governments, Canada included. Understandably, governments are looking to reduce expenses and in this context drug expenses represent what on the surface appears to be one of the simplest ways to cut costs. Drugs are generally a line item in the budget and are therefore easy targets- a percentage price reduction will translate into a corresponding and immediate reduction in expenses. However, this approach can be a pyrrhic victory of sorts as it fails to recognize the greater ecosystem of the industry and the consequences a simple price cut can have on the other parts of the system. Governments must adopt a more holistic approach that takes into account all of the economic and social benefits of drug development. In this context, one of BIOTECanada's objectives is to get governments to better understand the interconnectivity of the large, medium and small players and to see the health and economic benefits of developing therapies in Canada.

Tax policy is sometimes considered a better tool than direct funding. For example, a flow-through share regime used by the government might generate more savings if a biotech company was able to qualify for corporate federal tax rates. In that sense, would such a regime be useful for your members who need those finances?

Certainly tax measures are one way to provide an incentive for investment in research and development. The challenge is tax incentives represent a cost to governments. Canada's government has signaled they are in fiscal restraint mode and are not likely to extend flow through shares or look at creating any new tax incentive measures any time soon. But tax measures are only one possible undertaking. There are many other policy initiatives that carry little or no cost and will serve to attract investment and innovation. Regulatory streamlining would be a good example of such an initiative. In this context, BIOTECanada is working with the government to find other ways to attract capital and innovation to Canada. This really circles back to the earlier discussion regarding the establishment of a competitive public policy framework to attract capital investment. You need to find a way to reward investment in the industry in Canada. However that reward is structured, the industry would welcome it, since you are essentially putting out the welcome mat. Successfully growing a company in Canada will ultimately lead to the growth of new companies, which in turn grows the industry.

Startup companies generally have easy access to finances, but once clinical trials commence, it is more difficult to get those funds. Would you agree with that?

Drug development is a very expensive and time-consuming process. Depending on the type of therapy and testing needed it can require upwards of a $1 billion and 15 years before a drug is commercial, if a company is lucky- many therapies eat up significant capital and time but never even make it into the marketplace. Recognizing the significant cost and risk associated with drug development, the industry has understandably changed its business model to where pipeline development is done through partnerships and strategic investment. Some capital might be easy to get early on because the risks are lower. However, once clinical trials are underway the costs rise dramatically. Innovative funding mechanisms and partnerships are needed to overcome some of the costs, risks and extended development timelines. Venture capital and angel investment can certainly play a role but at a certain point that capital will back away because clinical trials are not their area of expertise. It certainly speaks to the complexity and timelines of the industry. Finding ways to bridge the investment gap and enable partnerships is certainly a role BIOTECanada plays in support of its members.

Do you bridge the gap between your members as an association?

Absolutely. An important role BIOTECanada plays is to provide a table for the development and nurturing of the partnerships and relationships emerging between the large, medium and small companies, all of which are members of BIOTECanada. The association behaves like a matchmaking table. At BIOTECanada meetings, large multinational companies sit across the policy table from the smaller domestic companies. This is an attractive proposition for all BIOTECanada members, regardless of their size or corporate structure.

What is your assessment of the Quebec-Ontario life sciences corridor?

Quebec and Ontario will always be the central engines to Canada’s economy, regardless of the industry: the greatest populations are centered around Toronto and Montreal, and the greatest access to the US and EU markets, two of Canada’s primary export markets, are through these cities. This is an important strength for the Canadian economy and this industry. However, an equally important strength of Canada’s biotech sector is the existence of many companies in strong clusters located in every region of the country from coast-to-coast. Over and above the well-known industry clusters of Toronto and Montreal, cities like Vancouver, Saskatoon, Mississauga, Winnipeg, Halifax, Calgary, Edmonton, Quebec City and Charlottetown are home to thriving industry groups. Each cluster leverages the strength of their region to grow companies. As I travel across the country and get to know the companies in these regions I have been impressed by how they all try and contribute to their local biotech cluster either through mentorship or investment. This self-nurturing is an important strength of the clusters and I believe it will pay significant

dividends going forward.

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