

Boosting Canadian success in the life sciences sector could mean more jobs and investment, a healthier economy and healthier people.

So what's holding us back?

Pharma Innovation

Acknowledging recent federal budget support for life sciences as a positive step for Canadian innovation, Canadian pharmaceutical industry leaders also expressed concerns that current measures fall short of those required to make Canada a contender in this knowledge-intensive industry.

Beyond funding for Genome Canada, the Canadian Institutes for Health Research and the National Research Council Canada Regional Innovation Clusters, the budget also announced tax changes intended to help Canada's biopharmaceutical industry.

In addition to applauding new federal support for post-doctoral and clinical trials research Russell Williams, president of Rx&D, the association of Canada's Research-Based Pharmaceutical Companies says, "The government's tax changes have the

capacity to boost the flow of venture capital into Canada for biotechnology and biopharmaceutical companies."

Pfizer Canada president Paul Lévesque added, "Modifications to section 116 under the Canada-U.S. Tax Treaty will remove double tax filing requirements and administrative delays that have to date turned many foreign venture capital and institutional investors away from investing in Canadian biotechnology firms."

According to Statistics Canada data, Rx&D member companies are one of the leading funders and performers of therapeutic products research and are also the largest single source of health R&D research in the Canadian business enterprise sector.

As a leader in knowledge capital and innovation, the sector has enormous growth potential. To fully realize that upside, however, Mr.

Lévesque says, "Bold and concrete policy changes to support the growth of life sciences research in Canada are required, including better research funding and the promotion of public, private and academic partnerships."

While acknowledging Canada's fiscally constrained environment, Mr. Williams stresses the importance Canada's innovation performance.

Regrettably, he says, "Canada lags behind other advanced economies with respect to overall innovation and the commercialization of research, a position acknowledged by government."

To address this challenge Mr. Williams says the industry is advocating a multi-stakeholder approach to government's review of all federal support for research and development.

"Adopting world class intellectual property standards, creating a modernized

regulatory regime for medicines and vaccines that is consistent with best practices internationally, and reducing red tape so that patients have access to the right medicine at the right time are all measures that will stimulate innovation as well as help reduce other health care costs."

According to a report by Wyatt Health Management for Rx&D, Canada has fallen behind other developed countries in access to medicines, which is bad news for both health care and innovation. The report found that among developed nations, Canada and the U.S. "are in a virtual tie for last place compared to the other countries on public spending on pharmaceuticals."

George Wyatt, managing director, explains, "We have developed a complex bureaucracy: Health Canada looks at safety and efficacy, the Common Drug Review (CDR) or

Joint Oncology Drug Review make reimbursement recommendations to public drug plans, and even more assessments are conducted by other groups at the Canadian Agency for Drugs and Technologies in Health."

Beyond that he says the provinces then undertake reviews of therapeutics before making funding decisions. As a result, he says, "If you live in one province, you may have access to a medication you require, but if you live in a different province and rely on a public plan, you may not."

Mr. Wyatt adds, "Access to medication and a competitive intellectual property environment are linked, and as a result, Canada is at a competitive disadvantage."

He says improving our bureaucratic processes will help. "Delays in evaluation can be mitigated through a process called 'patent term

restoration.' If you do significant work on your drug, and prove the drug has value beyond the original approval, other countries grant extra patent life. We don't do that in Canada."

Mr. Lévesque urges, "To be up with the leaders, we must implement an IP regime that sets Canada apart. For example, data protection is currently eight years here, while it is 10 years in Europe. The recent healthcare bill adopted in the United States offers 12 years for biologics."

He adds that another challenge facing industry is "branded pharmaceutical companies don't have an effective right to appeal court decisions under Canada's patent regulations."

Mr. Wyatt says, "In terms of intellectual property protection, if you invest in innovation, other countries recognize that effort. Canada does not."

"Bold and concrete policy changes to support the growth of life sciences research in Canada are required, including better research funding and the promotion of public, private and academic partnerships."

FIGHTING COMPLACENCY

Averting the next 'perfect storm' of childhood disease

By John Helou
General Manager,
Pfizer Specialty Care



Vaccines have turned horrible childhood diseases like polio, measles, mumps and diphtheria into distant memories. They've saved the lives of more babies and children than any other medical intervention in the past 50 years.

Their success, however, may be breeding complacency. New or emerging disease strains could have serious consequences on the health and welfare of tomorrow's population.

Pneumococcal disease (PD), which includes meningitis, sepsis, bacteremic pneumonia and other life-threatening conditions, poses such a threat. PD is the leading cause of vaccine-preventable death worldwide in children under five years, resulting in an estimated one million deaths per year worldwide. While PD vaccination programs have succeeded in reducing the risk, bacteria are stubbornly adaptive. An emerging strain called 19A is on the rise in Canada and around the world.

19A is highly resistant to several antibiotics and very difficult to treat. In Ontario, the first case of bacterial meningitis caused by 19A occurred in November 2007. The condition of the 14-month old patient was so perplexing and difficult to fight that 19A was dubbed a "Superbug" by the media.

Many experts see a 'perfect storm' brewing for the emergence of 19A. During 2008 in Quebec, the strain caused 48 per cent of all pneumococcal diseases in children under five, almost double the rate of 26 per cent the year before.

Before PD vaccination programs were introduced in Canada, the disease caused 15

Vaccination programs raise complex and difficult questions. What are the costs and risks to society and to the individual? How do we deal with those who refuse to be vaccinated and therefore place everyone else at risk?

deaths and 2,200 cases of pneumonia requiring hospitalization annually among children under five. Currently, provincial immunization programs use pneumococcal vaccines that do not cover important disease causing strains, including 19A. This is despite the fact that such a vaccine, Prevnar 13, exists today and could be readily available.

Consider for a moment the H1N1 pandemic and immunization program. While debate continues on both the threat and the response, many of us remember how otherwise young and healthy people were struck down by the virus, how it strained the capacity of some emergency wards and intensive care units, and how doctors and nurses were left helpless and frustrated as their best efforts failed to save their patients.

Vaccination programs raise complex and difficult questions. What are the costs and risks to society and to the individual? How do we deal with those who refuse to be vaccinated and therefore place everyone else at risk? When does an emerging threat merit a response?

For 19A, the answer to the last question is clear. It is a concern for every parent and physician – a potentially deadly infection that strikes the very young and is difficult to treat. It also may be preventable by vaccinating with Prevnar 13.

When it comes to deciding which vaccines to include in immunization programs, the voices of parents, physicians and other care-givers must be heard. Parents need up-to-date information on the threat from 19A, and should make their views known to health authorities.

A 19A 'perfect storm' may be brewing, but swift action will ensure we steer clear of it. ■

76%
Biopharmaceutical sector*

16.5%
Other

7.5%
Contract research organizations and generic drug makers**

Investing in Canada's future health

When it comes to investing in the discovery of new medicines and vaccines in Canada, the biopharmaceutical sector leads the way with both in-house and external research and development of over one billion dollars last year.

This message brought to you by:

Canada's Research-Based Pharmaceutical Companies

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Source: Statistics Canada, Industrial Research and Development: Intentions, 2009, Table 18-1, Research and development expenditures on therapeutic health products – By type of organization, 88-202-XWE, March 31, 2009. *Including Research-based pharmaceutical companies, biopharmaceutical companies and biotechnology companies. **Statistics Canada has not revealed expenditures on therapeutic health products for either "Contract Research Organizations" or "Generic pharmaceutical companies" individually in Table 18-1.

2 Genomic technologies are revolutionizing the drug discovery process, writes **Catalina Lopez-Correa**, Chief Scientific Officer, Genome Québec

3 Conference Board gives Canada a "D" in innovation

Pharma Innovation

EXPERT OPINION

Genomics – what the leading edge of health research means to Canadian’s and Canada’s pharma sector

By Catalina Lopez-Corra

MD, PhD, Chief Scientific Officer, Genome Québec



What is genomics? Simply stated, genomics is the branch of science that studies the genome – the genetic material of a given individual encoded in its DNA. In human beings, this genetic material is carried in our chromosomes which are located in each one of our cells.

The publication of the human genome sequence (the Human Genome Project) in 2003, constituted a major scientific turning point in the development of genomics. Now, with the information provided by this large multinational project, we are able to better understand how our genetic makeup influences our

health. More than 10 other human genomes have been sequenced and published since then and many more are now being sequenced, generating great amounts of data that are already having a strong impact on healthcare and medical practice.

On drug development, advances in genomic technologies and its applications are revolutionizing and impacting the entire drug discovery process. The biopharmaceutical industry is adopting genomic strategies for tar-

get discovery, efficacy and safety profiling as well as biomarker discovery and validation. As key contributors in the development of personalized medicines, pharmaceutical companies and other life-science players are becoming increasingly interested in developing biomarkers and companion diagnostics to help prescribe the right medication to the right patient at the right time and at the right dose.

The development of genetic tests is a new imperative tool to improve efficacy and safety profiles even more when one considers the enormous costs associated with drug discovery and the mounting costs of treating adverse drug events.

There are currently five companion diagnostic tests approved by the Food & Drug Administration that are required before using some

medications (e.g. CCR5-Selzentry for patients with HIV, EGFR-Erbitux for patients with head & neck cancer and for patients with colon cancer, HER2/neu-Herceptin for patients with breast cancer). Another 15 tests are now recommended by the FDA. The development of companion diagnostics is evolving rapidly and will be an essential element to our health care system to improve drug response and reduce costs.

Genetic biomarkers are used to stratify the individuals in a given population who will respond, or not, to some drug treatments. The development of specific genomic biomarkers already helps the development of targeted drugs with better efficacy and tolerability.

Large and well characterized patient cohorts are imperative to providing clinical vali-

dation of biomarkers. Accordingly, medical research needs access to genomic data in large sets of patients in order to unravel the genetic causes of common and rare diseases. As such, several countries, including Canada (CARTaGENE, led by Dr. Pavel Hamet), have launched large population studies that are well coordinated with international cohorts such as the Public Population Project in Genomics (P3G).

Many believe Canada has opportunities to develop unique approaches to personalized medicine, given its universal health care coverage, international leadership in human genetic research and access to provincial health databases for evaluation of safety and effectiveness of therapeutic interventions.

In his commentary *Personalized medicine: A transformative*

approach is needed published in the Canadian Medical Association Journal in February, 2009, Dr. Tom Hudson, president of the Ontario Cancer Research Institute wrote, “There clearly is a benefit to research in personalized medicine: prevention and screening strategies targeting high-risk individuals, avoidance of serious adverse outcomes, and better matching of therapies to disease and individual profiles.”

As such, genomics is providing a solid foundation for the development of tomorrow’s biotechnological tools. The stakes are high, since genomics is already unlocking the secrets to some of the major diseases of our times: cardiovascular diseases, diabetes, cancer and diseases of the central nervous system, like Alzheimer’s, to name just a few.

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Canada Research Chair weighs in on genomics’ future

“At present, the era of blockbuster medications where ‘one size fits all’ is on its decline.

Acutely aware of this reality and benefiting from huge progress of genomic, proteomic and biomarker research, the pharmaceutical industry, including its Canadian members, is progressively adapting to changing scenery by collecting and analysing pharmacogenomic data

aimed at improvement of targeting as well as avoiding individual side effects of novel medications.

Naturally, their studies are performed within populations selected for their specific clinical trial, best fitting to obtain needed information. In order to validate how such information will apply to general population, data from population based genetic studies, such as

CARTaGENE will become an essential asset to industry in translating from narrow clinical trial into general population to ascertain efficacy as well as safety of new therapies, on our way to more Personalised, Precision Medicine.”

Pavel Hamet, MD, PhD,
Canada Research Chair in Predictive Genomics

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UNTAPPED POTENTIAL

Conference Board gives Canada a “D” in innovation

Despite Canada’s scientific strength in biopharmaceuticals, researchers at the Conference Board and Canada and Fraser Institute warn that not enough is being done to foster development of this knowledge-intensive industry’s potential. “Canada needs to act quickly to capitalize on the opportunities presented by biotechnology,” says Gilles Rhéaume, vice president of Public Policy at the Conference Board of Canada. “We have major global market opportunities and we do world-class research. What is missing is a regulatory environment more conducive to getting drugs approved faster,” he explains.

Canada ranks 14th among 17 peer countries and continues to be a “D” performer on innovation in the latest Report Card by the Conference Board. Among other things the study notes Canadian pharmaceutical sales represent only about two per cent of global pharmaceutical sales. It also says despite some larger players the industry is still mainly composed of early-stage research companies, many of which are years away from clinical trials and even further away from significant revenues.

Dr. Brett J. Skinner, president and director of Health

Policy Research at the Fraser Institute, agrees that regulatory challenges are reducing economic growth in a key sector. “Biopharmaceuticals are a high-tech, knowledge-based industry. These are good, high-paying jobs we are losing.”

Dr. Skinner says the regulatory environment requires immediate attention. “Canada could speed up its regulatory process by taking advantage of the knowledge acquired in other jurisdictions. If Canada entered into agreements of ‘mutual recognition’ with other countries, new medications already approved in those countries could be introduced into the Canadian market more rapidly.”

Among his concerns Dr. Skinner notes an underappreciated consequence of this delay is that patients are not experiencing the potential health benefits that might otherwise result from earlier access to innovative new drug treatments. “There is no evidence other countries with faster approval processes are experiencing more adverse drug reactions,” he adds.

Dr. Skinner says approval delays also reduce the commercial value of drug patents in Canada. “Patents begin to expire when a drug is first discovered. Since it takes longer to get new medicines approved in Canada, patent

protection is effectively lessened. This is a competitive disadvantage for us.”

In addition, Dr. Skinner argues a lack of public funding of new medicines further reduces the commercial value of drug patents here. “Only a small percentage of the new drugs Health Canada certifies as safe and effective are finally declared eligible for reimbursement under provincial public drug programs. The provincial governments also take a long time to approve the few drugs they declare eligible.”

By contrast, he says, private drug insurance covers more new drugs, and covers them more rapidly. “Public reimbursement delays and denials diminish the potential economic returns from drug patents.”

Mr. Rhéaume explains that Canada is not yet taking full advantage of another opportunity. “The world market for regenerative medicine is huge. Canada, a leader in this developing science, has an opportunity to excel globally on this frontier.”

Regenerative medicine refers to techniques to re-grow damaged cells in organs and body parts such as knees and eyes. According to a Conference Board report these techniques are only a few years away from standard clinical

practice, and the market – driven by an aging population in the affluent countries – is growing. “Canada has a leading position in the science and a major opportunity to become a leader on this medical frontier,” says Mr. Rhéaume.

Looking forward, Canada’s ability to excel in biotechnology requires a more focused approach. “We need to establish an integrated biotechnology strategy that can encompass risk capital, highly skilled talent, and regulatory and policy changes,” Mr. Rhéaume.

“Canadians want us to be world class in life sciences research because they know success means more jobs and investment, a healthier economy and healthier people,” says Russell Williams, president of Canada’s Research-Based Pharmaceutical Companies (Rx&D).

Mr. Williams’ group agrees that Canada lags behind other advanced economies with respect to overall innovation and the commercialization of research. “Our industry welcomes the opportunity to work in partnership with government and other stakeholders to support R&D, in order to boost innovation and provide more economic opportunities,” he adds.

Focus on VIDO-InterVac public investment at work

A federally supported initiative that bridges a gap between university- and government lab-based health research and the private sector aims to be just the shot in the arm Canadian health innovation needs.

Formed in 2008 through a \$15-million federal investment, the Pan-Provincial Vaccine Enterprise Inc. (PREVENT) is a Centre of Excellence for Commercialization and Research administered by Canada’s Networks of Centres of Excellence program.

PREVENT’s job is to accelerate vaccine development for diseases for which no vaccine currently exists. Among its targets are prion diseases, respiratory diseases and severe diarrheal diseases. It is estimated that infectious diseases of medical significance cost Canada’s health care system more than \$3 billion annually.

PREVENT CEO Andrew Potter says, “There is a gap between research in universities and government labs and downstream development and commercialization by companies. PREVENT is designed to bridge it.”

Dr. Potter, who is also director of the University of Saskatchewan’s Vaccine and Infectious Disease Organization and new International Vaccine Centre (VIDO-InterVac), where PREVENT is headquartered, says, “We invest the time required to move vaccine candidates through the higher-risk phases of the clinical trial process, adding significant value with a minimal investment.”

PREVENT’s results are already showing. A vaccine candidate licensed by PREVENT is expected to enter Phase I clinical trials this year.

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PROGRESS

Results underscore value of health research and innovation

By advancing health research and the development of new therapeutics Canada’s biopharmaceutical industry is focused on improving patient outcomes. Here are just three examples of progress being made:

New therapeutics for people living with MS

Novartis Pharmaceuticals Canada Inc. has announced its entry into the field of multiple sclerosis therapeutics with its impending launch of two MS medications. An injectable disease-modifying treatment which has received a Notice of Compliance and will be launched in Canada in May 2010.

Novartis will offer a patient support program called ExtraCare, which will provide assistance to patients, who must self-inject the medication every other day. The program will

also provide extra services, such as consultation with allied healthcare providers.

Novartis is also expected to launch in the near future a new molecule, one of the first oral medications for MS patients. It will be sold as a capsule, freeing patients from the need to inject themselves.

Novartis is a leader in the healthcare field. Its entry into the MS therapeutic area furthers its commitment to the development of medications to improve the well-being of Canadians.

Research aims to help diabetes patients

With input from patients and healthcare professionals, sanofi-aventis Canada is about to complete an important research mandate on behalf of its parent company, headquartered in Paris. In 2009 Canada was chosen to conduct the first real-life observational study of patients using ClikSTAR, the newly launched, reusable insulin pen for patients who need long-acting or rapid-acting insulin.

The study, which involved 2,500 patients and 104 healthcare professionals, focused on ClikSTAR’s safety, its ease of use and overall patient satisfaction.

“Entrusting us with the research on ClikSTAR was a logical choice,” says Hugh O’Neill, president and CEO of sanofi-aventis Canada. “We’ve got a reputation for conduct-

ing reliable, quality studies. And insulin pens are widely used in Canada – by three-quarters of people who inject themselves with insulin, in fact.”

Study results are expected later this year. Sanofi-aventis will use them to refine and develop products and services for people with diabetes, who number more than 230 million worldwide.

“Managing diabetes can be demanding and time-consuming for patients,” says Mr. O’Neill. “Every incremental improvement we bring to their daily routines can make a big difference in helping them control their blood sugar levels and improve their quality of life. Their feedback will point us to the right patient-centred solutions.”

Advancing understanding of mental illness

According to the Canadian Mental Health Association, depression affects nearly three million Canadians and just six per cent of depression is diagnosed and treated effectively. Beyond the human suffering, the effect on economic productivity is enormous: Seven of every 10 people with major depression are in the workforce today, says Dr. Raymond Lam, director of the UBC Hospital Mood Disorders Centre. “Their productivity is way down because of their illness but they are not so impaired that it is obvious they need help.

“By establishing early identification, early intervention programs within work places, we

could significantly reduce personal distress and the bottom line burden on businesses.”

In support of that goal, Dr. Lam and his investigative team are conducting a six-month randomised controlled trial of escitalopram and telephone-based cognitive behaviour therapy. “For working people, not having to leave work for an appointment with a counsellor increases the likelihood of accessing treatment, and is particularly valuable in rural areas of Canada.”

The outcome of the study will be evaluated by assessing absenteeism and work productivity, response and remission rates, and quality of life.



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