

EDITORIAL OPINION

Innovation and drug safety - keys to better health outcomes

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By Russell Williams

Canada is at a crossroad in terms of establishing its position as a leader in pharmaceutical and biopharmaceutical innovation.

The federal government has recognized that Canada must be innovative if we are to be competitive internationally. In this regard, it has set an objective of making Canada one of the top five countries in the world in knowledge-based, innovative industries by 2010.

Getting there

To achieve this laudable goal, an important reality must be taken into account: intense competition between countries for new pharmaceutical investment.

There is no time to lose if we want Canada to win its fair share of international investment in research and development (R&D). All parliamentarians, regardless of political affiliation, should be in support of innovation, economic, and health policy. If not, investment intended for Canada will go elsewhere in the world. Already, we are missing opportunities for investment. We must be competitive. Canada can tread water for only so long before the inevitable happens.

The United States, the European Union, Japan and others are all working to attract new investment. Canada needs a better investment environment. If Canada is to win that competition for investment, it must ensure the business climate here is as good as or better than in these other countries.

Innovation is the key to Canada's continued economic success. In our global economy, knowledge provides competitive advantage. Knowledge increasingly drives new products and services and helps make our production methods and processes more efficient and effective. Knowledge increasingly drives the job market.

The research-based pharmaceutical community recognizes the value of innovation. We are ready to help lead the way to growth and prosperity. We are ready to help improve the environment in which innovation can flourish. We are ready with concrete suggestions that will make a difference both in health care and economic development.

Pharmaceutical research – achieving international competitiveness

Areas that will strengthen Canada economically and achieve increased international competitiveness include: better intellectual property protection, a better pricing policy that recognizes innovation, improved drug approval process, improved patient access to new medicines, and inclusion of the social sciences under the *Scientific Research and Experimental Development* (SR&ED) program.

Better intellectual property protection (IPP). From intellectual property flows innovation. Without protection the incentive to create new technologies and inventions is curtailed. This is particularly relevant for the research-based pharmaceutical community.

While Canada's patent protection for pharmaceutical discoveries stands at 20 years from date of filing – not 20 years from the time a medicine comes on the market – this overall patent protection is still less than what other competitive industrialized countries provide.

To ensure Canada remains competitive, Rx&D recommends Canada do what every other G-7 country has done: initiate patent term restoration to close the IPP competitiveness gap with other nations. Patents would then be extended by the extra amount of time it takes to develop, review and approve new medicines, up to a maximum of five years.

Second, another step to an improved innovation environment is to make the drug review process more efficient. On average, Health Canada takes about six months longer than the United States to approve new medicines. While the federal government has set aside funds to help address this issue, no positive results have yet been achieved.

Third, timely access to new medicines. The recent *Canadian Institute for Health Information* (CIHI) report highlighted the variations in drug expenditures and access by the provinces and territories across Canada. The reality is that some patients in one province have to wait years before they have access to a medicine that is available in another province. Canadians want access to new medicines as soon as they are approved by Health Canada. A recent survey by SES Research found that 83% of Canadians believe all new medicines approved by Health Canada should be made available under provincial drug plans.

Finally, an important change to the *Scientific Research and Experimental Development* program that encourages pharmaceutical research. At present, this tax incentive program fails to include research in the social sciences. The inclusion of social sciences would stimulate research-based pharmaceutical companies to work more broadly with Canadian universities in fields such as health economics and health care delivery research.

This plan will help Canada take its place as a world leader in life sciences innovation.

Value and benefit of medicines

Prescription medicines are also one of the most effective and least expensive resources for patient care. Medicines researched and developed by the innovative pharmaceutical community have saved our health care system billions of dollars over the years, and will continue to do so in the future.

In 2003, Rx&D estimated the patented medicines portion of health expenditures in Canada to be 6.5% or 6.5 cents of Canada's health care dollar. This is an effective investment when you consider medicines and vaccines save lives, avoid surgery, reduce and in some cases eliminate hospital stays, prevent disease, improve quality of life, and provide independence and autonomy by permitting people to stay with families and in their own surroundings.

Achieving a balance between safety and access

Transparency in the clinical trial process, leading up the drug review process by Health Canada, is fully supported by Rx&D. That is why Rx&D supports the creation of an international registry of clinical trials.

This is good news for patients who will be able to obtain more information about new medicines and therapies in development. Working in partnership with the international pharmaceutical community and Health Canada will ensure patients have access to all necessary clinical trial data, including benefits and adverse drug reactions.

The safety of medicines is absolutely paramount for Rx&D member companies as is the benefit medicines bring to Canadians.

Smart Regulation Report

Rx&D welcomes the federal government's *Smart Regulation Report on Actions and Plans* announced last month. The report highlights three areas of importance to patients, physicians, health care stakeholders, and the research-based pharmaceutical community in Canada: the timeliness, efficiency and transparency of the drug review process; the exercise of vigilance regarding the safety and therapeutic effectiveness of products currently on the market; and, access by Canadians to appropriately prescribed and cost-effective drug therapies.

This significant step forward to align Canada's regulatory system with other countries involved in innovation and the discovery of new medicines will benefit the federal government's objective of making Canada competitive internationally.

Our member companies are committed and ready to work in partnership with patients, stakeholders and governments to ensure the health care initiatives under the *Smart Regulation* will achieve what is best for those who matter most – patients. A better economy and better health outcomes for patients are certainly win-win situations for all Canadians.

Russell Williams is the president of Canada's Research-Based Pharmaceutical Companies (Rx&D). Prior to his appointment as Rx&D president, Mr. Williams was a member of the Quebec National Assembly for nearly 15 years, including service as the Parliamentary Assistant to the Minister of Health and Social Services.