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Canada's Research-Based Pharmaceutical Companies (Rx&D)

2015 Pre-Budget Submission

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Canada's Research-Based Pharmaceutical Companies (Rx&D)

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Introduction

Rx&D represents more than 50 research-based pharmaceutical companies who discover, develop and deliver new medicines and vaccines to Canadians.

Our members employ 15,000 Canadians in high-value, high-skill jobs, account for 46,000 jobs across our value chain and annually contribute $3 billion to the Canadian economy. In 2013, Rx&D members invested more than $1 billion in R&D – with 75% of this activity devoted to clinical trials – and approximately $322 million toward patient and community contributions.

Globally, the innovative pharmaceutical industry is the most research-intensive industry with over $135[1] billion invested into drug discovery, development and commercialization annually. In 2013, Booz & Co. ranked the world's top 1,000 publicly traded companies for innovation and 5 of the top 10 top and 7 of the top 20 R&D spenders were global Rx&D affiliates.

No other industrial sector consistently invests more in R&D, even in times of economic turmoil and financial crisis: annual R&D spending by the pharmaceutical industry is five times greater than that of the aerospace & defense industries, 4.5 times more than the chemicals industry, and 2.5 times more than the software and computer services industry.[2]

Today, Canada secures less than 1% of global R&D from the innovative pharmaceutical industry despite its status as a global leader in: peer-reviewed medical/scientific publications; world-class talent; and, modern facilities in which to conduct research and practice medicine.

It is because Canada – the Federal government alongside its provincial and territorial partners – has not made excellence in human health sciences innovation a national priority.

Budget 2015

Budget 2015– with federal finances returning to a state of balance – presents a unique opportunity to make targeted investments and decisions to ensure human health sciences innovation is a national priority and a strategic pillar of Canada's economic success.

Rx&D and its members are prepared to work in partnership with the Government of Canada, all parliamentarians and impacted stakeholders to shape and build upon this mandate. This submission recommends actions that will create a stable, predictable and globally competitive business environment to enable our members to bring innovative therapies to Canadian patients and continue to invest in Canada's world-class research infrastructure of people and institutions.

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[1] http://www.ifpma.org/fileadmin/content/Publication/2013/IFPMA_-_Facts_And_Figures_2012_LowResSinglePage.pdf

[2] http://www.ifpma.org/fileadmin/content/Publication/2013/IFPMA_-_Facts_And_Figures_2012_LowResSinglePage.pdf

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Clinical Trials: Our 21st Century Footprint

As noted earlier, over 75% of industry R&D is invested in clinical trials. These trials occur both in pre-market settings and increasingly, regulators and payers (public & private) are also requesting post-market surveillance and monitoring.

However, Canada continues to lag behind other industrialized and developed nations in its ability to attract and maintain clinical trials due to a variety of factors including cost competitiveness, multiple research ethics boards, patient recruitment and retention issues and an uncertain environment including our unpredictable intellectual property (IP) regime.

1) Rx&D recommends that the Government of Canada immediately move to implement all twelve (12) recommendations contained in the report entitled *Canada's Clinical Trial Infrastructure: A Prescription for Improved Access to New Medicines (November 2012) from the Standing Senate Committee on Social Affairs, Science and Technology (SOCI). The full report is found here:*
http://www.parl.gc.ca/Content/SEN/Committee/411/soci/DPK/01nov12/home-e.htm

A Globally Competitive Intellectual Property (IP) Regime

The Government of Canada is to be commended for achieving an important milestone in its *Global Markets Action Plan* with the signing of the Comprehensive Economic and Trade Agreement (CETA) Agreement in Principle.

The introduction of an effective right of appeal for innovators, implementation of patent term restoration, and the enshrining of eight years of data protection into the agreement sends an important signal to the global pharmaceutical community that Canada is committed improving its IP regime.

Nonetheless, the IP environment in Canada remains a challenge for Rx&D members. We are concerned with the Government of Canada's intent to "… end the practice of dual litigation" as noted in the CETA Technical Summary of Final Negotiated Outcomes released on October 28, 2013.

To date, Rx&D has received no clarification as to what the Government of Canada intends with respect to this issue, which could potentially undermine other existing IP rights. The lack of transparency with respect to "dual litigation" is also unfortunate, since increased uncertainty and instability within the IP regime may act as a disincentive to life sciences investments in Canada.

2) Rx&D recommends that the IP changes agreed upon in CETA be implemented immediately given that they are essential components of a historic international trade agreement. Any additional measures with respect to "dual litigation" should be the subject of a subsequent and transparent policy consultation process with interested stakeholders.

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In addition, Canadian case law related to the issue of patent utility is highly concerning and out of step with the standard applied in other developed nations.

3) Rx&D recommends that the Government of Canada work directly with industry on other IP issues – such as patent utility – which will likely be raised by our major trading partners in the context of other ongoing trade agreement discussions and with respect to Health Canada's planned orphan drug policy regulatory pathway which should be implemented as soon as possible and include appropriate exclusivity incentives.

Embracing Innovation

While Industry Canada has an explicit its mandate to enhance Canada's "innovation performance", the same cannot be said for Health Canada. When compared to its peers such as the Food and Drug Administration (FDA) in the United States which is "also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer and more affordable" or the European Medicines Agency (EMA) that "plays a role in stimulating innovation and research in the pharmaceutical sector", Health Canada lags with respect to a broader focus.

4) Rx&D recommends that the Government of Canada amend Health Canada's Mission, Vision, Core Values and Objectives to incorporate the promotion and acceptance of innovation into its culture, mandate, processes and procedures.

This recommendation aligns with recent federal intent signalled in public statements by the Minister of Health while respecting the constitutional jurisdictions in healthcare between the federal government and the provinces.

Accurately Recognizing the Value of Industry Investment

As part of its mandate, the Patented Medicine Prices Review Board (PMPRB) measures a portion of R&D activities undertaken by all pharmaceutical patentees – including Rx&D members – as published in its annual report to Parliament. This measurement substantially underreports the true level of investment made by our industry and as such, has misinformed government pharmaceutical policy decisions.

This underreporting is due to the fact that the PMPRB report is based on the application of a Scientific Research & Experimental Development (SR&ED) tax credit definition from 1987.

Pharmaceutical R&D has changed substantially since 1987 expanding beyond industry to include collaborations with universities, hospitals and other partners including pre-competitive research, bioethics, pharmacovigilance, comparative effectiveness trials and expenditures which are either not deemed eligible or are above SR&ED eligible thresholds.

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This issue places Canada at odds with its international peers as the definition of research eligible for SR&ED is inconsistent with the definition used by the OECD and our competitor nations to attract life sciences investments. The OECD's Frascati Manual is the international standard for the collection and reporting of national data on research and development (R&D) and this manual is currently being revised to recognize the constantly evolving nature of R&D in leading economies.

Canada must follow suit and accurately report the full extent of Rx&D member investments to strengthen its "brand" as a jurisdiction for global investment.

In June of 2014, Rx&D released its fourth consecutive supplementary R&D report[3] – compiled by KPMG – which shows PMPRB (with its outdated reporting methodology) failed to account for more than $322 million in R&D activity, a difference of 46%.

This conclusion is derived from a more modern set of criteria to measure pharmaceutical R&D, arrived at by Steering Committee of representatives of Industry Canada, the PMPRB, the Canadian Institutes of Health Research (CIHR) and Rx&D in 2010.

5) Rx&D recommends that the R&D criteria within the PMPRB's Regulations be expanded to include eligible research and capture all aspects of clinical research, direct investments in clinical trials, and complementary investments in other forms of research partnerships – as enumerated above – not currently eligible for SR&ED credits.

Safeguarding Confidential Business Information

In June, the House of Commons passed Bill C-17, *An Act to amend the Food and Drugs Act.* Rx&D has been publically supportive of the Bill as it essentially mirrors the manner in which our members already work with Health Canada.

However, prior to its passage, it was amended in an expedited clause-by-clause review with language that decreases the threshold for disclosure of confidential business information by Health Canada as it does not include a requirement for necessity or imminence of the safety risk in question prior to disclosure.

These amendments are inconsistent with the health and safety disclosure standards in other similar Canadian laws, such as the *Canada Consumer Product Safety Act* and the *Human Pathogens and Toxins Act.*

[3] http://www.canadapharma.org/CMFiles/Our%20Industry/Industry%20Facts/2014-06-20_RxD_RD_Report_FINAL_EN.pdf

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Parliamentarians need to be aware that such measures, if left unaddressed, will add greater uncertainty to the Canadian business environment and further harm Canada's "brand" for inward life sciences investments.

Building a Modern Policy and Regulatory Framework

Boosting investor confidence in Canada requires measures to ensure a stable, predictable, and cogent pharmaceutical policy and regulatory framework. Canada must make it a priority to align to global best practices of evaluation and risk management in order to achieve both the safest and most effective regulatory regime with the least cost and complexity.

While various types of regulation may be necessary at each stage of a product's lifecycle, the accumulation of these regulations causes the total compliance burden to become duplicative, unpredictable or inefficient for our members to address.

Rx&D is supportive of most aspects of Bill C-17 and we look forward to providing input specific to issue of Confidential Business Information, when it is studied by the Senate this fall. We also support regulatory harmonization initiatives with the US FDA – such as the common submission gateway – stemming from the *Regulatory Cooperation Council.*

6) Rx&D recommends that Health Canada adopt a modern and comprehensive legislative and regulatory regime for the assessment, approval, and monitoring of drug products in Canada. Rx&D further recommends that the Government of Canada align its regulations with international best practices of previous and ongoing regulatory harmonization activities.

7) Rx&D recommends that the Government provide the necessary resources and training to staff within regulatory bodies that review or assess pharmaceutical products – Health Canada, PMPRB, and the Canadian Agency for Drugs and Technology in Health (CADTH) – to ensure innovation is appropriately assessed in a timely manner so patient access to life-saving and life-changing technologies is not compromised. In addition, a public consultation of CADTH's Health Technology Assessment activities (with the Common Drug Review and the pan-Canadian Oncology Drug Review) should be undertaken immediately.

Working in Partnership

Experts such as Dr. Henry Friesen, former President of the Medical Research Council and the National Cancer Institute of Canada and Senator Kelvin K. Ogilvie, former President and Vice Chancellor of Acadia University and inventor of the "Gene Machine" have lamented the fact that Canada's healthcare system is silo-based both in policy goals and delivery mandates. As such, it fails to integrate and align health with innovation.

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8) Rx&D recommends the creation of an appropriately resourced multi-ministerial and stakeholder consultation framework to include Health Canada (and CIHR), Industry Canada, relevant federal funding agencies and stakeholders such as R7 organizations to work to align policies, programs, and public, private and charitable sector investments into federal health research, innovation, and commercialization efforts.

9) Rx&D recommends the creation of an appropriately resourced intergovernmental (federal/provincial/territorial) consultation framework including relevant para-public funding agencies to discuss and effectively align policies, programs, and public, private and charitable sector investments into national health research, innovation, knowledge translation and commercialization efforts.

Conclusion

We urge the Government of Canada to take decisive and coordinated action in Budget 2015 an implement our recommendations to make human health sciences innovation a national priority. We reiterate that we stand ready to work in partnership with the Government and other stakeholders to make this a reality.

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