



7333 Mississauga Road
Mississauga, Ontario
Canada L5N 6L4

Tel. 905 819 3000
Fax 905 819 3099
www.gsk.com

Submission to the Expert Panel on Review of Federal Support to Research and
Development

GlaxoSmithKline

February 18, 2011

Summary

By definition R&D (comprised of basic research, applied research and experimental development) is a subset of the broader term, innovation (which also includes commercialization). Canada has historically focused heavily on investing in early R&D elements but has neglected to adequately support the later elements including commercialization. This provides a likely explanation for why our world-leading investment in R&D (relative to GDP) has not delivered a reciprocal return on innovation and productivity. Instead of investing in innovation - we've been investing in R&D! We need to shift the focus, however, this doesn't necessarily mean shifting government funding out of the research pot since many of the necessary changes don't require a direct financial investment as much as they require that the right policy framework is in place to ensure that incentives to innovation are aligned and impediments are removed.

Summary of Recommendations

In order to enhance our global competitiveness Canada must increase its focus on all aspects of innovation (including commercialization) not only by aligning incentives but also by removing impediments.

Aligning Incentives

- **The SR&ED program is designed to provide indirect support (tax credits) and needs to be balanced to include direct support**
- **The administration of the SR&ED program should be improved to enhance its efficiency and attractiveness.**
- **The scope of the SR&ED program is limited and needs to undergo changes to keep up with the changing face of research and optimize its effectiveness.**

Removing Impediments

- **Adopt the world's strongest intellectual property regime.**
- **Use procurement policies to encourage innovation through the adoption of innovative products and services.**

Introduction

GSK is one of the world's leading research-based pharmaceutical and healthcare companies. We are among the top 15 private sector investors in R&D in Canada; contributing \$144M in 2009 alone. Together with our industry colleagues we collectively contribute over \$1.2B annually and are responsible for a disproportionate share of Canada's BERD. However as a Canadian local operating company of a multinational pharmaceutical firm we are finding ourselves progressively less competitive with our global counterparts. Our industry has several R&D issues that go beyond just a simple capital shortage in Canada. For example, we have also seen significant loss of clinical research and clinical trials to other jurisdictions. We need the support of academia and governments to build a partnership here that will maintain and build on clinical trial investment and on the broader research investment in Canada and in turn drive innovation.

It is important to note that this support doesn't always need to take the form of financial assistance. Often it simply requires a supportive policy environment, as history demonstrates. In the mid 1980's our industry was investing \$50 million annually in R&D in Canada. That has since grown to over \$1.2 billion annually as a direct result of policies which restored modest patent protection for pharmaceuticals in the late 1980's and early 1990's.

Therefore an argument can be made that the right policy framework could even reduce the need for certain financial investments by creating an even greater return.

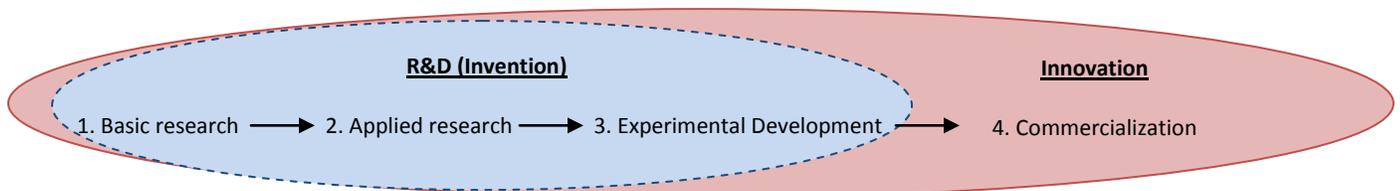
In their consultation document the Expert Panel on R&D (Panel) posed 15 questions to stimulate and guide our submission. While each of these address critical elements focused on improving Canada’s competitiveness in innovation, we at GSK have chosen to focus on four of these questions (within the body of our submission) which we believe best address our perspective.

R&D vs. Innovation

Q15. Is there a difference between R&D and innovation? If yes, how are they different? Should government focus on R&D or Innovation? What should the balance be?

Definition of Innovation: The OECD definition of innovation, as referenced by the Panel, is “the implementation of a new or significantly improved product, (good or service), or process...”ⁱ So by definition the invention must be implemented (*at the customer level*) and must bring (*new or significantly improved*) value to become an innovation. This is further supported by the R&D commercialization ecosystem model which says that “Inventions are not considered to be business innovations until they achieve significant commercial penetration”ⁱⁱ. Clearly the Coalition for Action on Innovation in Canada had it right when they suggested that innovation “encompasses much more than research and invention”ⁱⁱⁱ.

Definition of R&D: The OECD definition of R&D, as referenced by the Panel, includes three activities: Basic research, Applied research and Experimental Development but it falls short of including Commercialization, which as we’ve seen is an important element of innovation. Therefore by this definition R&D is not the same as innovation rather the former is only a subset of the latter.



As the panel acknowledges, Canada’s investment in R&D has traditionally been intentionally focused on basic research with increasingly dwindling support as we move to the right of the model with little to no focus on commercialization.^{iv}

Perhaps this explains Canada’s dilemma. We are among the world leaders in Government investment in R&D (as a percent of GDP) yet significantly lacking when it comes to private sector investment (BERD) and innovation.

Canada has disproportionately directed its efforts at the R&D end of innovation and missed the important commercialization element.

So why is commercialization so important? Because unless we support and encourage commercialization, private investment in R&D (BERD) will go elsewhere, as we are seeing.

What does it mean to change the focus of our efforts? We do not believe we should ignore the R&D aspects and move all our investment over into the commercialization side of innovation. Rather, as the panel correctly identifies, we need to adjust the balance. However this doesn’t necessarily mean shifting government funding out of the research pot since many of the necessary changes don’t require a direct financial investment as much as

they require that the right policy framework is in place to ensure that incentives to innovation are aligned and impediments are removed.

In order to enhance our global competitiveness Canada must increase its focus on all aspects of innovation (including commercialization) not only by aligning incentives but also by removing impediments.

1) Aligning Incentives to Improve Innovation

Q10. If you have direct experience and knowledge of the SR&ED tax credit, what are your views in relation to the following: current structure, strengths and weaknesses of refundable portion and simplifying administration?

Financial support serves as an incentive only when it is aligned to the needs of the R&D investor. The Canadian government is generous in its support of R&D through its many programs but it's most significant, the Scientific Research & Experimental Development Tax Incentive Program (SR&ED) fails to serve as an optimal incentive in attracting R&D. In order to optimize the Government of Canada's Investment in this program we recommend the following changes with respect to structure, scope, and administration

i) Structure of SR&ED: As indicated by the Council of Canadian Academies, Canada is unique in its high degree of reliance on tax-based incentives to support R&D^v, and SR&ED is the most significant of such programs. In contrast to Canada, "the US spends significantly more on direct support measures in comparison to support through tax incentives. Furthermore Sweden, Finland, and Germany offer no R&D tax credits as incentives to companies conducting R&D, preferring direct support measures exclusively"^{vi}.

The SR&ED program is designed to provide indirect support (tax credits) and needs to be balanced to include direct support.

- **Increase the emphasis on direct (pre-tax) support measures rather than the heavy reliance on indirect support (tax credit) measures to enhance the ability of multinationals to compete with foreign counterparts and to support start ups.**
- **Replace after tax credits with pre-tax support to financially incent local operating companies.** The success of a Canadian affiliate of a multinational corporation is measured on the overall commercial success of its operations with operating profit/pre-tax profits as the measure. An increased emphasis on direct commercial support measures that will drive the overall success and profitability rather than the heavy emphasis on indirect support (i.e. tax credits) will enhance the ability of multinationals to compete with foreign counterparts.

ii) Administration of SR&ED: SR&ED is designed to incent R&D yet is often administered in a manner which discourages or disallows *bona fide* research. Clearly audits are necessary to prevent abuse and protect the best interests of the Canadian tax payer; however a number of measures should be put in place to satisfactorily improve these processes while maintaining the integrity of the program.

The administration of the SR&ED program should be improved to enhance its efficiency and effectiveness.

- **Increase focus on the "intent" of the SR&ED program rather than on minor disqualifying technicalities.** The CRA often disallows projects based on technicalities in the contracts and paperwork rather than looking at the substance of the situation (i.e. is R&D actually being performed in Canada).

- **The CRA should be provided sufficient resources to allow them to ensure timely completion of audits.** (Many audits routinely take 3-5 years to complete, thus decreasing business certainty and consequently R&D incentive.)
- **Further clarify qualifying versus non-qualifying activities and expenditures to ensure that the claims being submitted are as accurate as possible.**
- **Establish clear guidelines regarding acceptable levels of infrastructure expenses.** (i.e. specify the percentage of qualifying direct expenditures that could be claimed as overhead cost thus reducing the need for overhead audits)
- **Ensure audit scopes are well defined.**
- **Broaden the use of process audits to reduce the need for multiple project audits.**
- **Conduct sample audits.**

iii) Scope of SR&ED: SR&ED's narrow definition has failed to keep up with the changing face of research and consequently does not capture important existing R&D or incent further such work.

The scope of the SR&ED program is limited and needs to undergo changes to keep up with the changing face of research and optimize its effectiveness.

- **Broaden the scope of SR&ED eligible research to include health outcomes research.** The demand for health outcomes research has created an important shift in the nature of medical R&D; however the SR&ED program fails to acknowledge this type of work. A conservative estimate suggests the level of *bona fide* outcomes research in which our industry currently invests could be as much as 25% of our reported SR&ED eligible research^{vii}. Furthermore, governments and payers are demanding more real world, health outcomes data before adopting our innovations and this is all part of the experimental development process. Therefore we are required to perform this research, we do perform this research yet we are not credited for it.
- **Expand the scope of SR&ED to include more infrastructure and administrative expenses.** The establishment of an R&D capacity in Canada requires significant incremental infrastructure and administrative expenses yet many of these are not considered SR&ED eligible.

2) Removing Impediments to Innovation

Q 13. Are there any gaps in the Government of Canada's support to business and commercially-oriented R&D? Do firms performing R&D in other countries have an advantage over Canadian firms because of access to programs that are not available in Canada?

i) Intellectual Property Protection (IPP): According to the Coalition for Action on Innovation in Canada a "robust climate for innovation is only possible if Canada's regulatory processes encourage the development and launch of innovative products and if our laws ensure that inventors and those who invest in their ideas can fairly reap the rewards of their work. Canada should aim for a reputation as the best place in the world in which to reap the rewards of their work."^{viii} Currently Canada's intellectual property regime provides less effective protection to innovators than those available in other advanced economies across all sectors.

Adopt the world's strongest intellectual property regime. Canada must take advantage of current opportunities (Canada-European Comprehensive Economic & Trade Agreement) to improve intellectual property protection thereby creating a more attractive environment for investment in innovation in Canada. Specifically in order for the Canadian pharmaceutical sector to ensure global competitiveness and world class health research innovation Canada must:

- **Provide an effective appeal mechanism under the Patented Medicines (Notice of Compliance) Regulations.** Under the current regulations the generic manufacturers always have a right of appeal while innovators do not have an effective appeal process. Changes to these regulations (permitting the innovators a right of appeal) are needed to restore balance and ensure generic firms' allegations of patent invalidity are appropriate.
- **Ensure current "data protection" regime is vigorously defended to avoid additional IPP instability.** Canada's current data protection regulations, which are already less rigorous than our European and US counterparts, are currently subject to legal challenges by generic manufacturers. In order to ensure some degree of stability, predictability and global competitiveness there needs to be a vigorous federal government defense of our current regulations.
- **Ensure Patent Term Restoration (PTR) meets those of our G7 competitors.** Currently Canada is the only G7 nation without critical PTR which allows innovators to recover part of the patent term lost through the lengthy development and regulatory process.

Q 6. Regarding the creation of demand for business innovation, what role, if any, do you believe that government should play in being a "first customer" for R&D investments in Canada?

ii) Adoption of Innovative Products and Services: A fundamental element of encouraging innovation is that local governments need to become early adopters of innovative products and services. "Unfortunately government purchasing process generally discourages new and smaller ventures, and policies are biased against unproven products. By contrast, the United Kingdom has since 2008 required each government department to establish an Innovation Procurement Plan setting out how it will embed innovation procurement within its purchasing practices and make use of innovative procurement mechanisms."^{ix}

- **Use procurement policies to encourage innovation through the adoption of innovative products and services.** For our sector specifically, Canada is not buying or nurturing the fruits of pharmaceutical innovation in the way other countries are. The major purchasers of pharmaceuticals in Canada are government drug plans, yet Canada ranks 23rd out of 29 in countries which are actually buying our products when we bring them to market and it ranks 26th out of 29 countries for first in class products^x. **Thus there is a major destructive dichotomy – as a country Canadian governments and citizens are investing in health sciences research capacity (the majority of which will lead to pharmaceutical inventions) but on the other hand provincial procurement policies, through the drug programs, are discouraging the commercialization of these new medicines and minimizing the potential fruits of this research.**

Conclusion

In order to enhance our global competitiveness Canada must increase its focus on all aspects of innovation (including commercialization) not only by aligning incentives such as SR&ED credits but also by removing impediments, such as non-competitive intellectual property protection and government procurement practices.

ⁱ Review of Federal Support to Research and Development (2011), *Expert Panel Consultation Paper*, p. 5.

ⁱⁱ Review of Federal Support to Research and Development (2011), *op. cit.*, p.8.

ⁱⁱⁱ John Manley and Paul Lucas. *An Action Plan for Prosperity*. Coalition for Action on Innovation 2010. p. 1.

^{iv} Review of Federal Support to Research and Development (2011), *op. cit.*, p.5.

^v Science, Technology and Innovation Council (STIC, 2009) (reference re: reliance on tax credits) p. 21.

^{vi} Council of Canadian Academies (CCA) (2009), *Innovation and Business Strategy: Why Canada Fall Short?*, p. 19.

^{vii} Deloitte (2007) statistical survey of Rx&D member companies

^{viii} *An Action Plan for Prosperity* (2010), *op. cit.*, p. 4.

^{ix} *An Action Plan for Prosperity* (2010), *op. cit.*, p. 5.

^x Canada's Research-Based Pharmaceutical Companies (Rx&D 2010), *The Rx&D International Report On Access to Medicines* (IRAM), p. 26.