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Expert Panel
Review of Federal Support to
Research and Development
1200-270 Albert Street
Ottawa, Ontario
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Subject: Submission to Expert Panel on Research and Development

Dear Expert Panel:

Merck Canada Inc. (MCI) is pleased to have the opportunity to make the following submission to the Expert Panel on the important subject of Federal support to research and development in Canada.

We have a long and very proud history in Canada and are sincerely interested in working with the Federal government to identify opportunities to enhance Canada as a R&D destination within the pharmaceutical and life sciences industry.

A. Background

Merck Canada Inc., headquartered in Kirkland in West Montreal, is one of Canada's leading research-based pharmaceutical companies and possesses a long record of innovation. The company employs 1432 people. Merck Canada Inc. invests more than $70 million annually in research and development and is one of the top 20 corporate R&D spenders in Canada.

Merck Canada Inc. is a recognized leader in the treatment of asthma, osteoporosis, glaucoma, prostate disease, migraines and infectious diseases. The company also markets an extensive line of cardiovascular products for high blood pressure, elevated cholesterol and heart failure as well as a broad range of vaccines.

Merck Canada Inc. is a leading member of Rx&D – Canada's Research Based Pharmaceutical Companies. We have played a major role as a member and as a company in engaging in public policy development aimed at ensuring a vibrant, growing, productive and world class innovative pharmaceutical industry in Canada. Rx&D has submitted a response to the Expert Panel which Merck Canada Inc. supports.

Like many of our industry counterparts, we are under increasing international competitive pressures, loss of market due to key products coming off patent and a continuous erosion of access for our products to the Canadian health care system.

We welcome the Federal government review of its support for research and development and the creation of an expert panel to conduct that review. We believe that, based on the recent decline in Canada's competitiveness in keeping and attracting innovative pharmaceutical industry R&D, we – industry and governments, have little time for inaction once appropriate policy options are identified.

B. Observations

For a number of years, MCI and Rx&D have engaged the Federal government on the subject of the evolution of Canada as a location in which to invest. In particular, we have emphasized the need to have policies in place that encourage innovative investment in research and development.

The resultant benefits of such investment are clear:

- challenging and high paying jobs for well educated, young Canadians;
- the opportunity to collaborate on research into promising new therapies;
- the ability to do so with colleagues in our company in and from various countries and in research and academic institutions across Canada;
- being part of the development of new technologies that have health outcomes and commercial value;
- improving the lives of Canadians and people in developed and emerging world economies.

We have also advised successive governments that, while welcomed, it is insufficient to simply fund basic research via various granting councils and create limited tax based incentives to conduct private sector research (SRED).

The world in which companies like ours competes has changed over the past ten years. The Federal R&D support programs and policies now in place are inadequate and growing more so every day in the face of the focused, aggressive and purposeful policies of jurisdictions with which Canada competes for its share of world wide R&D.

Canada is approximately 2% of the world pharmaceutical market. Canada conducts approximately 1% of the world pharmaceutical R&D. That imbalance must be addressed.

However, the innovative pharmaceutical industry in Canada is finding it harder every year to meet its objective of investing 10% of gross revenues in R&D. (The fact that the PMPRB measurement of such expenditures is well known to underestimate their dollar value is a separate and ongoing irritant to the industry.)

It is with deep regret that we report MCI recently lost 200 extremely well educated researchers from our Montreal labs. We could no longer justify that investment in Canada. The work they were doing will unfortunately be conducted elsewhere. Their departure reflects the changed reality of conducting research in Canada, the changing market for our products as well as the comparative cost-effectiveness of conducting that research on a consolidated basis elsewhere.

While our industry faces growing offshore competition for R&D spend, all governments within Canada seek new ways to limit the access of our new, safe and cost-effective technologies to patients and prescribers. There is linkage between market access and our ability to justify current and increased expenditures on R&D. This has, however, yet to be acknowledged and addressed by governments whose stated objective is increased R&D.

For those on the panel looking at the issue of increased pharmaceutical and bio-pharmaceutical R&D in Canada, it will be critical to understand that innovation is part of a continuum with critical breakpoints along that continuum where public policies – of many types, can and do impact the viability of research based pharmaceutical companies like MCI.

To focus exclusively on the very basic aspects of R&D without understanding these critical elements is to miss most of the story of the determinants of pharmaceutical innovation.

C. Issues – Recommendations

1. Tax Based Incentives – the most common Federal tax based incentive available to MCI is the SRED - the Scientific Research and Experimental Development tax credit which, in the case of MCI, provides for an income tax deduction for eligible R&D performed in Canada. This incentive supports cost based basic tax deductibility opportunities in Canada and Quebec that all firms are afforded, as well as the important corporate income tax incentives associated with declining tax rates.

   The reality is SRED is very much overestimated by policy makers with respect to both its relative and, specific to our industry sector, competitive impact.

   The narrow definition of eligible activities and restrictive evaluation criteria do not reflect the activities in which we must engage. As much as 25% of “research” activities associated with meeting regulatory requirements and demonstrating post-approval safety and efficacy (to various levels of Canadian government and their agencies) is not currently eligible. This applies to certain types of clinical research and clinical trials and related investments in research partnerships.

   The panel should consider an expanded definition of eligible activities that reflects the reality of the new pharmaceutical R&D paradigm and at the same time addresses the current unpredictability and adversarial nature of the SRED application adjudication process. Our industry association, Rx&D has provided the panel with suggested improvements.

   A refundable wage credit for R&D workers should be assessed for its potential to positively impact pharmaceutical R&D in Canada.

2. Intellectual Property Protection – Canada is non-competitive in the most fundamental of policy areas as related to encouraging domestic pharmaceutical and bio-pharmaceutical R&D, i.e. intellectual property protection. There is little point in encouraging more R&D activity and innovation if the results of that work receive inferior protection. IP internationally is a moving target. Assuming that because Canada 10, 15 or 25 years ago enhanced pharmaceutical and bio-pharmaceutical IP to world class levels of the day

that this is sufficient in 2011 is a serious mistake. Established and emerging countries against which Canada competes for MCI investment dollars have aggressively improved their IP protection.

Canada is deficient in the following eminently correctable ways:

- We lack the capacity for innovative companies to appeal decisions on patent regulations notwithstanding the fact that generic copiers have that right. This fundamental matter of natural justice must and can be corrected. If it is not corrected, it sends the message to decision makers elsewhere that Canada does not provide fair and equitable patent protection.
- Data protection, i.e. protecting the intellectual content of innovators drug submissions from being used by copiers to gain unacceptable early entry to the Canadian market for a set period of time, must be strengthened to that of EU and US standards.
- Given the growing length of time for health and safety regulatory review and approval, and the layering of more time for pre-market access reviews, Canada needs to establish a policy of Patent Term Restoration as is the case in other jurisdictions. This would recognize lost market access time and provide commensurate extended patent terms for such affected therapies.

3. Regulatory Efficiency - critical to an industry with very long lead times from bench to market (up to 15 years and on average 12) is the time spent in regulatory review for safety and efficacy of our products – pharmaceuticals and vaccines. While having improved, by Canadian standards, in recent years we still face non-competitively long wait times for submission reviews by Health Canada. And the vagaries of too frequent application of unique assessment criteria by Health Canada submission reviewers, confronts us with issues not considered germane by other international regulators. Attempts are under way now to modernize this system. There is little point in trying to support R&D and advocate for more commercialization of the results of that work, if Canada (a small market as noted) continues to be viewed as slow and unpredictable.

   The greater harmonization of review criteria and processes as well as learning from other well recognized jurisdictions and their regulatory decisions should be encouraged.

4. Market Access – the prospect of spending hundreds of millions of dollars on R&D, clinical trials and regulatory review only to have access to the market for approved products blocked is a serious disincentive. Neither MCI nor any other innovative company expects to be compensated for less than effective and cost-effective products.

   However, when agencies such as CADTH and the Common Drug Review (both partially funded by the Federal government) make product listing recommendations to Federal and Provincial drug plans that result in Canada being ranked 26 out of 29 developed countries in new drug and vaccine therapy uptake, that is a huge disincentive to companies like MCI.

   A serious assessment of the role of CADTH/CDR should be conducted from the perspective of its impact on investment decisions and its impact on the Canadian health care system beyond the narrow focus of cost containment.

5. Public Health Investment Certainty – MCI and other companies that develop and produce vaccines know that these important therapies will be used by the publicly funded health care system in large measure. Knowing that a market will exist for such product is an incentive for ongoing R&D aimed at the improvement to, and creation of, new vaccines. Canada needs to commit to a long term, well funded national vaccines strategy and program in conjunction with the provinces and territories. Vaccines are exceptionally cost-effective and their development should be encouraged.

Merck Canada Inc. values the opportunity to provide the Expert Panel with this submission. Should the panel have any questions or wish to follow up with us on the observations and recommendations we make, we would be a happy to receive a request to do so.

Yours truly,

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