

## Pharmaceuticals – Life Sciences as an Economic and Competitiveness Driver

### Background

Knowledge-based industries, such as innovative pharmaceuticals, are recognized as engines of the new economy and will help Canada achieve its stated goal of a world leadership position in health innovation. Governments are striving to enhance our competitiveness and the economic base in which the discovery, development and commercialization of new innovations can thrive. At the same time, policymakers are seeking to moderate and control healthcare expenditures.

A robust innovative pharmaceutical industry will result in “health and wealth”, in the form of better patient outcomes, job creation and a strong economy. Innovation can contribute to all of the principles and objectives that a healthcare system might strive for. Pharmaceutical research and development into innovative medicines contributes value to the health of Canadians by helping them to live longer and more productive lives. Patient care is best served by making new innovations rapidly available. New medicines save valuable dollars by helping to reduce the number of expensive hospitalizations and surgeries.

Industry investments into research and development of innovative new medicines have the additional benefit of enhancing economic growth within the knowledge-based, life sciences sector, creating new high value highly skilled jobs, and can create a competitive advantage for Canada in adapting and implementing world class technologies as they become available.

The evolving global context is very challenging. Other nations are competing aggressively in a global marketplace with Canada for the same innovative pharmaceutical jobs and investments. However, the potential for growth is huge. With two and a half percent of the total global sales, Canada currently accounts for only one percent of global pharmaceutical investments. It is time for the federal and provincial governments to establish a favorable climate for increased research and development and investment in this key part of the knowledge based economy by following and implementing the recommendations set out below.

In order to create a business friendly climate for the pharmaceutical industry to increase its investment in Canada, several crucial aspects must be addressed:

- Improved protection of intellectual property
- Rapid and fair access to markets
- A globally competitive regulatory environment.

### Recommendations

That the federal government:

1. Ensure that Canada’s pharmaceutical intellectual property protection regime is “best in class” in all material respects with the regimes of Canada’s key competitors, including without limitation instituting increased data protection for innovative biologics, patent term restoration, and stable and predictable intellectual property protection with meaningful enforcement mechanisms. In particular, equity and balance must be restored under the *Patented Medicines (Notice of Compliance) Regulations* by providing innovators with a right of appeal in the event of an unfavorable decision. Each of the recommended intellectual property improvements is described in greater detail in *“Innovation for a Better Tomorrow: Closing Canada’s Intellectual Property Gap in the Pharmaceutical Sector”*, (Canadian Intellectual Property Council, 2011).
2. Ensure that the Common Drug Review (CDR) moves to adopt the recommendations of the House of Commons Standing Committee on Health and recognizes the Government of Canada’s support for these recommendations:

- Undertake a third party evaluation
- Strive for greater openness within the various stages of the CDR process consistent with practices elsewhere in Canada and globally, including convening expert committee hearings in public
- Strive for a meaningful appeals process
- Establish the appropriate used and weighting of evaluation criteria to incorporate social and ethical values for the review of innovative medicines, including first-in-class medicines and medicines for rare disorders.

Related to the recommendations above, a key element is to improve access to drugs in federal programs as well as in provinces and territories by establishing a Patient Wait Times Guarantee (PWTG) for pharmaceuticals, with a defined timeframe and evidenced-based benchmarks for making decisions around reimbursement.

3. Review the mandate, governance and work of the Patented Medicine Prices Review Board (PMPRB) given that it has now been in existence for more than 20 years. The goal of such a review should be to ensure that the Board is performing a valuable service within its statutory mandate to Canadians without adding an undue regulatory burden or hindering the trade and industrial development objectives of the federal government.

Ensure that the PMPRB annual review of R&D spending by the patentees includes an updated definition of R&D as well as the research conducted by the biotech companies themselves (which are investing large sums in R&D in their own rights, but it is not captured because they are not marketing patented products).

4. Continuously strive to increase the efficiency and sustainability of the federal drug review and approval processes while at the same time maintaining and assuring safety and efficacy in accordance with Health Canada regulations.
5. Encourage greater international harmonization of standards and sharing of scientific review information with leading regulatory authorities.
6. Adopt a more efficient approval process for prescription drugs, , but continue to maintain and ensure safety, according to Health Canada regulations.
7. Amend the *Income Tax Act* to broaden the definition of what qualifies for Scientific Research and Experimental Development (SR&ED), with the objective of encouraging further investments in R&D and improving Canada's global competitiveness for attracting these types of investments. One potential measure could include expanding the definition of SR&ED to include research in the social sciences as contained in the OECD definition. Furthermore, the administration of the SR&ED credit could be streamlined and made more predictable for claimants.