April 15, 2024

Maximilian Baylor
Director General
Business Income Tax Division
Department of Finance Canada
90 Elgin Street
Ottawa, ON K1A 0G5
Email: SRED-PB-RSDE-RPB@fin.gc.ca

Ref: SR&ED Review

Dear Mr. Baylor,

On behalf of Innovative Medicines Canada (IMC) and its membership, I am writing with respect to the consultation to modernize and improve the Scientific Research and Experimental Development (SR&ED) tax incentives in order to encourage research and development (R&D) that benefits Canadians.

IMC is the national association representing the voice of Canada's innovative pharmaceutical industry. The association advocates for policies that enable the discovery, development, and delivery of innovative medicines and vaccines to improve the lives of all Canadians and supports the members' commitment to being a valued partner in the Canadian healthcare system. The association represents companies which support 107,000 high-quality, well-paying jobs in Canada and collectively, our members contribute $15.9 billion per year to Canada's knowledge-based economy.

The innovative pharmaceutical industry is among the most research-intensive sectors, and IMC members are among the largest private sector research funders in Canada. In 2020 alone, the innovative research and development pharmaceutical sector in Canada invested $2.4 billion in R&D, including $1.3 billion in in-house R&D[1].

As the federal government undertakes its review of the SR&ED tax incentive program to focus on cost-neutral improvements, we offer the following comments.

Existing Program Highly Discretionary and Creates Uncertainty

There is significant variability in the way that the SR&ED program (the program) is currently administered, which undermines the potential benefits and deters innovators from accessing the program. There is little clarity around what constitutes an eligible activity or expense. As a result, eligibility determinations are largely subjective, vary across Canada, and depend greatly on the individual Canada Revenue Agency (CRA) reviewer. Different auditors allow for different types of activities which creates significant commercial uncertainty and increases administrative burden.

[1] https://www150.statcan.gc.ca/n1/pub/11-621-m/11-621-m2023001-eng.htm

Historically, sectoral guidelines that were co-developed by the CRA and industry helped achieve a common understanding. Unfortunately, such guidance has been archived and can no longer relied upon. To maximize the program's potential and optimize the societal benefits resulting from continued innovation, new guidance should be issued with an expansive approach to research and development. For example, any investment spent on research, including those spent in the post-market phase (open label studies, real world evidence, etc.), should be eligible under the program. Such activities constitute continued research and contribute to further innovation. Similarly, it is important that Canadian affiliates of global companies that spend on, or partner with other Canadian institutions for research activities in Canada, are considered eligible. The pharmaceutical industry is highly regulated, and there are very specific requirements with respect to the operation of clinical studies that may incidentally render the activity outside the scope of eligibility for the SR&ED program but would otherwise meet program requirements in principle. IMC members would welcome modernized policies that provide greater certainty for all parties involved.

Additionally, it would be helpful for such new guidance to establish clear review processes. Currently, IMC understands that there are no specific timelines that auditors must follow, despite clear deadlines for claimants. It is also challenging for claimants to seek a second opinion or speak with a specialist within the CRA to make representations as to whether an activity or expense is eligible. In addition, there should be a more efficient dispute resolution mechanism in circumstances where innovators disagree with CRA's assessment, rather than initiating litigation which diverts company resources away from the R&D activities, and which also consumes government resources.

Finally, to improve efficiency and reduce the need for a second opinion, IMC requests that a dedicated CRA team with expertise in the life sciences sector be established. Previously, large life science claimants had case managers who had institutional experience. These case managers provided a level of continuity and reduced the significant administrative burden to establish a base understanding on scientific matters, which has unfortunately increased now that new auditors are assigned to each project.

Need for a Thoughtful Approach to Incentives that Prioritizes Innovation

We note that for any individual firm, its unique circumstances will dictate their views on the relative importance of SR&ED in their overall research and development decision-making process. A Canadian-based preclinical start-up will have different considerations than an established multinational biopharmaceutical manufacturer, which will need to take into account global tax regimes and incentives offered in other jurisdictions. Regardless of their size, level of experience, and head office location, companies operate in the Canadian research ecosystem with broadly similar goals: to develop and market medicines to improve people's lives.

Today's pharmaceutical research landscape is far removed from the historical model of large, centralized in-house research facilities. There is a significant and growing focus on collaborative models of innovation with partnerships among public and private research institutions. This includes the emergence of clustered networks of academic and research institutes – along with start-ups and spin-offs, commercialization centers and virtual research labs that combine skills and knowledge across disciplines and distance. These research activities are not always well-suited to, or captured by, SR&ED credits.

The availability of SR&ED credits is just one element in the complex decision-making process for global pharmaceutical research investments. To effectively support a diverse range of firms with varying sizes, capabilities, and resources, it is essential to adopt a broad approach to incentives. This approach should be motivated first and foremost by the goal of promoting science and innovation. While specific incentives can provide short-term benefits in certain circumstances, they are insufficient drivers of competitiveness without a holistic approach.

We therefore recommend a number of linked areas of concentration for future policies in this area:

a) Tailored incentive programs that address specific industry needs, such as tax credits, grants, and research partnerships.

b) A coordinated strategy that considers the broader commercial environment, including market dynamics, the efficiency and predictability of regulatory frameworks, and global competitiveness, as essential to maximize the impact of incentives and drive sustainable growth across sectors.

c) A focus not only on incentivizing R&D investment but also on improving downstream market operations, streamlining commercialization pathways, and optimizing overall product reimbursement timelines.

By addressing these broader factors, Canada can attract and retain investment, stimulate innovation, and strengthen its position in the global marketplace.

Market Conditions and Attractiveness for Investment

Efficient market operations are critical for attracting investment and fostering sustainable innovation. Canada's attractiveness as an investment destination depends on multiple factors such as the quality and timing of reimbursement, intellectual property protection, regulatory predictability, access to funding and talent, and support for commercialization.

Drug reimbursement timelines and lifecycles have long served as barriers to entry in Canada and weakening R&D prospects domestically as a result. The time between regulatory approval for new drugs and their listing on public provincial formularies averaged 736 days in 2022, double the average time reported in comparable OECD countries[2]. This is a significant headwind for Canada's global competitiveness in life sciences. By improving these aspects, Canada can enhance investor confidence, stimulate R&D activity, and accelerate the pace of innovation across sectors.

Additionally, the Government of Canada's *Biomanufacturing and Life Sciences Strategy* (BLSS) should be leveraged to reinforce research infrastructure, nurturing collaborations between industry and academia, and strengthening support for activities related to commercialization and expansion. By aligning endeavors with the objectives outlined in the BLSS, Canada can position itself as a prime hub for life sciences investment and innovation, thereby attracting substantial investment to propel product development from initial investment to commercialization.

[2] Access and Time to Patient: Prescription Drugs in Canada. Ottawa: The Conference Board of Canada, 2024. (Data from IQVIA)

PMPRB R&D Reporting

This consultation presents an opportunity to highlight a decades old policy anomaly and unnecessary duplication. The *Patent Act* and *Patented Medicines Regulations* require the Patented Medicine Prices Review Board (PMPRB) to collect and report information on research and development relating to patented medicines. For this purpose, patentees must track and report expenses that would qualify for SR&ED tax credits as defined on December 1, 1987.

Using the 1987 definition substantially undercounts the amount of R&D activity of IMC members. Statistics Canada now compiles a more appropriate accounting of pharmaceutical R&D, which was upwards of $2.4 billion invested in R&D in 2020, representing an increase from the previous year.

The PMPRB approach creates substantial administrative burden for our members. If a patentee is claiming the current SR&ED credit, this is a highly duplicative effort because it requires tracking expenses against two different SR&ED definitions. If the patentee is not claiming the SR&ED credit, then it is a mandated task only for the purpose of producing a report that demonstrably under-measures research activity and is widely acknowledged as inaccurate.

After 1990 Canada experienced substantial expansion of both the economic footprint of innovative companies and the health research enterprise in Canada. There is no doubt, however, that there have been substantial and profound changes to the business model and regulatory environments in Canada and globally. The measurement and reporting tool used by PMPRB, tied to an outdated 1987 SR&ED definition, needs to change.

Conclusion

IMC appreciates the opportunity to provide feedback to modernize and improve the SR&ED tax incentives. The current consultation presents an opportunity to address critical policy anomalies and foster a conducive environment for innovation and investment. IMC remains committed to exploring ways with governments, health research institutes, biotechnology companies and researchers to expand our R&D and investment footprint in Canada in the coming years.

Thank you for considering our input. Should you require any further clarification or additional information, please do not hesitate to contact me.

Sincerely,

Declan Hamill

Vice President, Policy, Regulatory and Legal Affairs