Canadian Pharmaceutical Manufacturers and Exporters Alliance
Alliance des fabricants et exportateurs pharmaceutiques du Canada

Director General
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Department of Finance Canada
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Via email : SRED-PB-RSDE-RPB@fin.gc.ca

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Re: Second Phase of SR&ED Consultation

On behalf of the Canadian Pharmaceutical Manufacturers and Exporters Alliance (CPMEA), I am pleased to submit our comments on the Second Phase of the SR&ED Consultation.

The CPMEA represents Canadian pharmaceutical and biopharmaceutical manufacturers operating production facilities in Canada, making medicines for Canadian patients and for export. Its members are Canadian corporations headquartered and paying tax in Canada. The SR&ED program is critical to our industry to encourage investment in technology and scientific development.

As it stands, however, our member companies have experienced great uncertainty and inconsistency with SR&ED claims adjudication. The critical medicines that we produce are largely generics and biosimilars, requiring significant investment in research and development, technology, and human studies[1]. Yet, Research and Technology Advisors (RTA) are often inconsistent in their evaluation of activities, dismissing expenditures used to create products that are the 'same' as existing products. CRA audits of activities are overly onerous and produce contradictory results, adding to uncertainty and compliance issues.

There appears to be a fundamental misunderstanding by CRA staff of the nature of the type of research undertaken to produce a new generic or biosimilar medicine. The regulatory and technical requirements to bring a generic or biosimilar product to approval are rigorous and unique and have changed over the years.

Products are much more complex and testing more extensive. Routes of delivery are more complicated, such as injectables; or may require devices, such as autoinjectors or inhalers. R&D to repurpose, reformulate or combine known molecules can provide value-added medicines with therapeutic improvements for unmet needs. Significant investment is required in R&D activities for generic and biosimilar products; often the same types of activities undertaken by the originator for which SR&ED credits were allowed. For example, generic versions of Nasonex®. Furthermore, regulatory requirements have changed over time and there are many

[1] To be approved by Health Canada, generics and biosimilars must prove that they are bioequivalent to the originator product and can be used interchangeably.

additional R&D activities needed for the approval of generic and biosimilar medicines that were not required when the originator product was approved.

Tax Policy and Drug Manufacturing

Tax policy is an important contributor to the sustainability of our industry and our ability to continue to manufacture critical medicines for Canadians.

Shortages of medicines are an ongoing global problem for developed nations like Canada. Covid 19 shone a bright light on our reliance on other countries for medicines and the importance of having local production.

Recognition of the importance of domestic production of essential medicines as a requisite for public health and national security is growing around the world. Greece, for example, has implemented a program to reduce the claw-back (or rebate) paid to the national drug program for companies that invest locally in R&D activities. The European Union, through its Critical Medicines Alliance, is working with the generic and biosimilar industry towards strategies to boost national manufacturing, to build resiliency in the medicines supply chain, and ensure sovereignty of source.

In the past Canada has had a rich history of drug manufacturing with a significant number of companies that produced pharmaceuticals in Canada. As a nation, we exported large volumes to the U.S.; as recently as 2016, Canada had a trade surplus with the U.S. in pharmaceutical exports.

Sadly, over the last 8 years, domestic production has declined, and pharmaceutical products manufactured in Canada now account for only 12%[2] of the finished products consumed by Canadian patients. Most of the production in Canada is by generic and contract manufacturers, without whom Canada's pharmaceutical supply chain would be extremely vulnerable.

The impact of this loss of local manufacturing is unfortunate especially at a time of increasing geopolitical tension. Canada's heavy reliance on imported medicines creates a potentially catastrophic vulnerably in the supply chain. If Canadians cannot depend on domestic production to meet their needs, we are facing a looming national security and public health crisis.

The loss of domestic production has also taken with it reductions in capacity, investment, and expertise. Increased reliance on imports has also contributed to job loss in the sector. This is not any easy problem to fix; it can take years to bring production back online due to the unique nature of drug manufacturing, permitting, regulatory compliance, and the lengthy Drug Establishment Licensing (DEL) process.

[2] Canadian Generic Pharmaceutical Importing/Manufacturing Capacity Study, Ernest and Youn; 2021. https://canadiangenerics.ca/wp-content/uploads/2022/02/02.22-EY-CGPA-Capacity-Study_FINAL-1.pdf. pg. 21

With these factors in mind, **we recommend that the Department of Finance consider tax strategies to ensure the sustainability of local production and to promote the manufacturing of medicines in Canada.** In addition to enhanced SR&ED credits, examples of tax strategies that would support the industry include:

- A manufacturing tax credit for manufacturers of essential medicines based on the value and intensity of the activities performed in Canada.
- Restoration of the preferential tax treatment for pharmaceutical donations by corporations for medicines manufactured in Canada.
- Repeal of the phase-out of the Accelerated Investment Incentive and increases to the Manufacturing and Processing credit.

Second Phase of SR&ED Consultation: Questions

With respect to the questions as part of the second phase of the SR&ED consultation, we have some specific recommendations:

Question 3: How should the concept of "Canadian" public corporations be defined, should the government proceed with measures to improve access to the SR&ED program's enhanced credit for Canadian public corporations?

- We recommend that the Department of Finance consider expanding eligibility for the enhanced rate to Canadian companies with foreign ownership and Canadian public corporations. Ownership structure should not be relevant for SR&ED tax credits. The purpose is the same – to encourage investment in Canada in activities which promote innovation and scientific discovery. Additional tax credits will help attract funding from public markets and/ or foreign direct investment that is often difficult to attract in Canada. A beneficial tax rate for SR&ED, could encourage companies that undertake SR&ED activities to headquarter in Canada.

Question 8: Would it be preferable that the government make the general rate refundable, but at a reduced rate? What would be an acceptable trade-off in this regard?

- We recommend maintaining the general non-refundable rate at the current level; and create an option for a lower but refundable general rate. Companies could choose the best rate for their circumstances.

Question 9: In your view, should SR&ED-eligible activity be broadened from the existing OECD definition of SR&ED, generally used by Canada and other countries offering R&D tax credits? If so, how would you propose to amend the current definition? Why would any additional activities warrant government support?

- We recommend that the SR&ED-eligible activities be broadened. Many capital expenditures are very specific and necessary to support R&D activities and should be considered in a more fulsome way as a part of the SR&ED program.

- Expenses for quality control and testing of materials, devices, products or processes should also be included as eligible for SR&ED credits.

Question 10: Can you provide specific examples of activity that you think should be eligible for the SR&ED program that are not currently eligible? Would such a change bring additional predictability to claimants?

- We recommend the government revert to the pre-2014 SR&ED program changes:
  - Restore the 100% credit on amounts paid to Canadian subcontractors (instead of the current 80%)
  - Reintroduce eligibility for the purchase and rental of equipment, as well as for capital expenditures.
- We recommend that a special project be undertaken to collaborate with generic and biosimilar drug makers who manufacture in Canada to understand the unique nature of their R&D activities. There is opportunity to provide greater understanding and education for assessors who may not have experience with R&D expenditure related to the development of these critical medicines and the evolving regulatory environment in which they are brought to market.

Question 12: To what extent do businesses face financial challenges and trade-offs in protecting their intellectual property (IP) in Canada and abroad? Would it be appropriate for the government to provide additional support to these activities under the SR&ED program? If so, what would be a cost-effective approach?

- We recommend that any changes to the SR&ED program that consider IP protection should not disrupt the important balance in Canada's IP regime between rewarding innovation and encouraging competition. Any SR&ED benefits to patent holders should not in any way harm those who market off patent products.

We invite the Department of Finance to take this submission as an invitation to engage with the Alliance. We hope you will work with Canadian producers of medicines to understand how tax policy could be used to make Canada more self-sufficient in medicines and reduce our dependency on imported products.

Sincerely,

Terry Creighton
President,
Canadian Pharmaceutical Manufacturers and Exporters Alliance – Alliance des fabricants et exportateurs pharmaceutiques du Canada

The Canadian Pharmaceutical Manufacturers and Exporters Alliance – Alliance fabricants et exportateurs pharmaceutiques du Canada (CPMEA) is a new trade alliance representing pharmaceutical companies that manufacture in Canada. We have come together in an Alliance to tell the story about drug production in Canada and to raise awareness of the unique issues facing our industry. The CPMEA founding members are Apotex Inc, Pharmascience and Laboratoire Riva.