



Health Canada Consultation on Removal of reconsideration process from requests for priority review and advance consideration for Notice of Compliance with conditions

Joint Patient Group Response

Save Your Skin Foundation, on behalf of signatory patient organizations, is pleased to provide this submission in response to Health Canada on its proposal to remove the reconsideration process from requests for priority review and advance consideration for Notice of Compliance with conditions.

Background

As stated in the Guidance for Industry-Priority Review of Drug Submissions, the history of NOC/cs comes from the hard work of the HIV/AIDS community in the early 1990s. Even though successful treatments became available in 1996, people with AIDS were still dying in Canada because the then drug review process was too slow. Other countries had already recognized this in their policies, but Canada lagged behind. Finally, the then Minister of Health, the Honourable Allan Rock brought in NOC/c. It saved many lives. Since its use for HIV, the NOC/c has been used for other life threatening and seriously debilitating diseases, many of which are listed on page 10 of the Guidance document. It has continued to save many lives.

The premise behind this policy is that for these diseases waiting for a full set of data takes too long to save these lives. To compensate for the fact that there may not be a complete set of evidence, conditions are placed on the manufacturer to continue to study the treatment being conditionally approved and to ensure that ultimately there will be robust evidence to continue to approve the drug for sale in Canada. If it does not meet that threshold, approval for sale can be revoked.

This policy is about saving lives where these groups of people are desperate.

If this policy change is implemented, it removes an avenue for a small number of drugs that affect these patients in crisis to have a second chance to get a drug. You have stated that only 6% of drugs are submitted for reconsideration and only 8% of those results are amended. Surely it is not too much to ask Health Canada to keep open this avenue for the small number of seriously ill people whose lives are at stake.

It is noteworthy that the number of priority reviews are approved in Canada is far fewer than those approved in other comparable jurisdictions such as PMDA, Switzerland and Australia. This accounts for at least some of the requests for reconsideration.

Recommendation 1: Health Canada should retain the present process permitting a reconsideration from requests for Priority review and advance consideration for Notice of Compliance with conditions.

Rationale

The time required to review 6% of rejected review requests is surely manageable within the present Health Canada structure. Although only 8% of those seeking reconsideration have led to decisions being amended, given that these are requests for badly needed therapies that treat life threatening or seriously debilitating conditions, each approval has a profound impact on the patients with the disease under review. No patient group should be precluded from the opportunity to access these therapies for procedural reasons alone, *i.e.*, the lack of a reconsideration process. While patients support a more focussed and more efficient regulatory review process, that can never be at the expense of potential access to a badly needed treatment by a patient. A fulsome review in what are a few cases should never be sacrificed in any situation for efficiency.

There are substantive issues that could lead to a request for reconsideration including the interpretation of submitted scientific data, applied methodology, the relative weight given to data and its impact on the risk/benefit assessment, the application of Guidance or internal processes or Health Canada's unwillingness to accept a science-based alternate approach to one set out in the Guidance document. Health Canada should be prepared to support its decision-making process.

Recommendation 2: In cases where Health Canada declines a positive response after reconsideration, it should publicly post its decision and the reasons for the refusal.

Rationale

Transparency in Health Canada decision making is a cardinal rule. The sponsor and other interested parties are entitled to understand the decision-making process and reasons for the decision, including whether Health Canada was limited in its ability to apply new methodologies that more comprehensively consider risk/benefit, complexity and uncertainty.

In addition to ensuring due process, this also gives the sponsor the opportunity to amend its application to meet the standards required for a resubmission should it wish to do so.

Recommendation 3: Augment the evaluation process for priority review and NOC/c to include more and early engagement with applicants and/or provide more detailed guidance for submissions based on lessons learned from the reconsideration process.

Rationale

Health Canada's decision and guidance materials do not indicate how many reconsideration requests were related to interpretation of submitted scientific data, applied methodologies, and relative weight given to data and its impact on the risk/benefit assessment. It is also unclear if and how Health Canada's application processes would consider or allow for modern or alternative approaches. If Health Canada removes the ability of innovators to provide evidence based on the latest methods, science, and technology, Canadian patients will be at a disadvantage compared to jurisdictions where bidirectional mechanisms exist to support innovators and the regulator.

Recommendation 4: Publish data on:

- Number of health products impacted in the last 10 years by amendments to reconsideration requests
- Number of patients impacted in the last 10 years by amendments to reconsideration requests
- Number of times issues were raised by the reconsideration process as well as the type of issues outlined as reasons for reconsideration
- Disease areas impacted by refusal and reconsideration decisions
- Type of applicant that requested reconsideration (academic-led innovators vs. SME vs. MNE)

Rationale

These data would help to inform innovators and academics about how to better develop submissions and may be used to inform Health Canada's application and decision-making processes.

Sincerely,

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Jackie Manthorne, President and CEO, Canadian Cancer Survivor Network

Trudy Flynn, Chair of the Board of Directors, Fibromyalgia Association Canada

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Dana Gies, Executive Director, Canadian Skin Patient Alliance

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About the Signatory Organizations

Save Your Skin Foundation

Save Your Skin Foundation (SYSF) is a national patient-led not-for-profit group dedicated to the fight against non-melanoma skin cancers, melanoma and ocular melanoma through nationwide education, advocacy, and awareness initiatives. Save Your Skin Foundation is committed to playing an active role in reducing the incidence of skin cancer in Canada, and to providing compassionate support for all Canadians living with skin cancer.

Access to Treatment and Innovation Oncology Network (ACTION)

Access to Treatment and Innovation Oncology Network (ACTION) is a national coalition of oncology patient groups with the mandate Patient groups work together to promote greater education and understanding of therapies to ensure that Canadians have equal, timely and equitable access to these therapies, companion diagnostics, and supportive care.

All.Can Canada

Led by patient groups and people with lived experiences of cancer, All.Can Canada (ACC) is a national, multi-stakeholder network for cancer care efficiency, with a preliminary aim of optimizing people's entry into cancer care through a swift, accurate, equitable, and appropriately delivered diagnosis.

The Quebec Cancer Coalition

The Quebec Cancer Coalition (*Coalition priorité cancer au Québec*) is a Coalition of over 75 non-profits in oncology who seek to improve public policy and improve the health-care system for people affected by cancer. Since 2001, it has sought to be a strong voice for patients, survivors and caregivers from all regions of Quebec, across all cancer types and all stages of the disease.

The Leukemia & Lymphoma Society of Canada

LLSC is a national charitable status organization dedicated to finding a cure for blood cancers and its ability to improve the quality of life of people affected by blood cancers and their families by funding life-enhancing research and providing educational resources, services, and support. The Leukemia and Lymphoma Society of Canada is the largest charitable organization in Canada dedicated to blood cancer.

Our focus includes:

- Funding research from bench to bedside.
- Rethinking how a person navigates their blood cancer experience
- Providing targeted blood cancer information
- Offering tools for psychological and emotional support
- Empowering Canadians to take charge of their blood cancer experience through practical support and advocacy

Gastrointestinal Society

The Gastrointestinal Society is a national charity committed to improving the lives of people affected by digestive and liver conditions, including cancer, obesity, and rare diseases. We provide trusted, medically-sound information, support research, and promote appropriate patient access to healthcare. Together with our partner organization, the Canadian Society of Intestinal Research (CSIR), we are proud to celebrate our 50th Anniversary this year, continuing our unwavering dedication to individuals from coast to coast to coast.

Migraine Canada

Migraine Canada transforms the lives of people affected by migraine and headache conditions, leading national advocacy, education, and support initiatives for over 4.3 million affected Canadians.

Canadian Council of the Blind

The Canadian Council of the Blind is a membership based organization which strives to improve the quality of life for those living with vision loss and in the prevention of blindness. We work continuously to ensure medication is developed and administered quickly to prevent blindness.

Canadian Cancer Survivor Network

The Canadian Cancer Survivor Network was created by a group of Canadians concerned about cancer and cancer survivorship issues.

Mission:

- To promote health by conducting educational activities for cancer patients, caregivers, and survivors on the physical and financial impacts, and other relevant topics, associated with managing cancer.
- To promote health by providing individuals living with and survivors of cancer, and their caregivers, with access to related counselling, information, or support group programs.
- To advance education by organizing and participating in conferences and speaking engagements to the public on topics related to cancer.
- To advance education by conducting research on cancer patients' and survivors' physical, emotional, and financial well-being and disseminating the results of the research to the public.
- To undertake activities ancillary and incidental to the attainment of the above charitable purposes.

Fibromyalgia Association Canada

Fibromyalgia Association Canada (FAC) is a national, volunteer-led nonprofit organization dedicated to improving the quality of life for Canadians living with fibromyalgia. FAC works to build a unified national voice to increase awareness, support research, provide patient-led education, and advocate for better recognition, resources, and funding for people with fibromyalgia and their families. FAC serves the fibromyalgia community across Canada in both English and French.

Pancreatic Cancer North America

Pancreatic Cancer North America (PCNA) is dedicated exclusively to changing the outcomes and experiences of people facing pancreatic cancer. Since 2006, we have led with urgency and purpose, working to improve survival and quality of life by funding high-impact research, delivering trusted patient and caregiver programs, and advocating for systemic change. PCNA exists so that no one faces pancreatic cancer alone or without access to expert, compassionate, and equitable support.

Canadian Skin Patient Alliance

The Canadian Skin Patient Alliance (CSPA) is a registered charity and non profit organization that improves the health and well-being of people across Canada affected by skin, hair and nail conditions. Founded in 2007, CSPA supports this mission through collaboration, advocacy and education initiatives for the skin patient community. As there are thousands of different skin conditions – and more than 1,000 rare skin diseases – CSPA helps bridge the gaps among the public, patients and their loved ones, healthcare professionals, and researchers. To further support our patient communities, we work with our Affiliate Members, a formal network of over 30 Canadian patient organizations. CSPA envisions a world where people affected by skin, hair and nail conditions live healthy and fulfilling lives.

AYA CAN

AYA CAN is a peer-led national organization advocating for Canadian adolescents and young adults (AYA) affected by cancer. Our mission is to advocate for an equitable and integrative system of care to improve the experiences of Canadian adolescents and young adults affected by cancer.