August 6, 2020

VIA EMAIL SUBMMISSION: requests@cadth.ca and CC PatientEngagement@cadth.ca.

Director, Pharmaceutical Reviews
Canadian Agency For Drugs And Technologies In Health
865 Carling Ave
Ottawa, ON K1S 5S8

Dear Members of the CADTH,

ALS Action Canada is a new patient-led initiative advocating for urgent access to promising therapies for Canadians living with ALS. We are submitting our feedback to you on the CADTH "Proposed Alignment of CADTH Drug Reimbursement Review Process. June 2020."

We write to you as Canadians with Amyotrophic Lateral Sclerosis (ALS). We are the nation's doctors, firefighters, lawyers, teachers, business owners, executives, military members, and tradespeople. The day we were diagnosed with ALS we were sent home to die. Today, this will most likely be due to the fact that new promising treatments will be delayed by an lengthy Canadian drug approval process.

BACKGROUND: PATIENT EXPERIENCE

Eighty per cent of people with ALS die within two to five years of being diagnosed. The twenty per cent who live longer usually rely on a ventilator through a tracheotomy, communicating only with their eyes, described by the ALS community as living in a 'glass coffin'.

To date, there have been few meaningful treatments approved for ALS and recent experience has overwhelming shown the process takes too long. Edaravone, the most recent therapy to be approved, took nearly three years from the time of application to Health Canada to provincial reimbursement approval, and two provinces have yet to approve it for coverage. The time elapsed from when Edaravone was approved by Health Canada until the first province, Quebec, approved this drug was 574 days. In this time 1700 ALS patients died. This represents a crisis for ALS Canadians.

Current scientific progress has given the ALS community legitimate hope for the first time. Now there are over 160 drug companies working on ALS projects: there are several promising ALS therapies in the late stages of the clinical trial pipeline. The reality, however is that all of this activity has been largely happening outside of Canada. Canadian patients are faced with a crisis of hope as despite the scientific breakthroughs, the current Canadian drug approval process is longer than the expected lifespan of an ALS patient.

The current Canadian therapy approval process often exceeds the expected lifespan of an ALS patient because:

(1) Canada is not a first choice for pharmaceutical companies and on average there is a nine-month delay between FDA approval and an application to Health Canada;

(2) Health Canada then begins its six-month review and in the Proposed Alignment of CADTH Drug Reimbursement Review Process-June 2020 the time taken for CADTH approval of all drugs is a maximum of 180 days, roughly the equivalent to 553 Canadian ALS lives lost. While it is understood that sponsors may apply to have their candidate therapy submitted simultaneously to both Health Canada and CADTH such that the Priority Review by Health Canada and the simultaneous review by CADTH may combined take six months rather than a cumulative process of perhaps twelve months if the sponsor were to apply to each agency consecutively; and

(3) Finally, the therapy must be approved by each province via a process that fails to appreciate the life-expectancy of an ALS patient. Given this federal and provincial approval process patients can wait almost three years to access new therapies. Three thousand Canadians with ALS will die in this time.

ISSUE

1. Canadians need immediate access to promising therapies that are approved in other countries. Six months to the ALS Community is unnacceptable. The ALS Community is currently collaborating with Health Canada and multiple stakeholders to establish a multinational agreement, similar to oncology's Project Orbis, to enable simultaneous ALS therapy approvals from both the FDA and EMA. CADTH will be expected to rapidly adjust their review process to ensure they are not the limiting factor in expedient ALS therapy approval;

2. In Section 5.2 of CADTH's Draft it is stated that drugs are processed in the order in which they are received. Drug Approval Review by CADTH should have an expedited and separate process which identifies, prioritizes and reviews drugs for RARE TERMINAL diseases like ALS;

3. In Section 8.1 of CADTH's Draft we note that there is no expert committee on RARE TERMINAL diseases yet there is one for oncology. We believe that there should be an expert committee for RARE TERMINAL diseases. We want to ensure that any drugs received by the expert committee for ALS include ALS specialty clinicians, and Canadian persons living with ALS;

4. In Section 8.6.2 we notice that only sponsors and drug programs are eligible to file for reconsideration of a drug after a failed initial approval. We understand that if patient groups are also allowed this prerogative then the time for reconsideration is extended but we feel there should be room for a patient led appeals process; and

5. Section 8.6.4 of the Draft refers to the fact that in a reconsideration hearing, a teleconference only is allowed. We are requesting that a Record of Decision including rationale is available in the interest of Open Government and modern governance

practices. We believe that the patient groups should be able to be witness to the credentials of the “expert team members” and have input into the selection of those “experts.”

Yours truly,

Deane Gorsline (587) 983-8056
Chair, ALS / SLA Action Canada
alsactioncanada@gmail.com

Bill Duff, Executive Committee Member, ALs / SLA Action Canada
Jan Mattingly, Executive Committee Member, ALS / SLA Action Canada
Kerry Winkler, Executive Committee Member, ALS / SLA Action Canada
Greg Gowe, Executive Committee Member, ALS / SLA Action Canada
Rick Wilson, Executive Committee Member, ALS / SLA Action Canada
Barb Gorsline, Executive Committee Member, ALS /SLA Action Canada

Cc: Francis Drouin, MP, Chair, ALS Caucus
Ms. Tammy Moore, CEO, ALS Canada