ALS Society of Canada
Société Canadienne de la SLA
www.als.ca

September 20, 2021

Ms. Alysha Croker
Office of Paediatrics and Patient Involvement
Health Products and Food Branch
Health Canada

Dear Ms. Croker:

Thank you for your September 8 response to my inquiry about Health Canada's review period for the new ALS therapy Relyvrio. We will be sharing your letter on our social media channels to keep the ALS community informed given the significant interest in and need for access to proven ALS therapies. Since this is the ALS Society of Canada's first exchange with the Office of Paediatrics and Patient Involvement, I wanted to take the opportunity to provide additional context that I hope will prove helpful.

As you are aware, we were surprised to learn that Relyvrio was not granted priority review. While I understand Health Canada policies may have affected this decision, that the manufacturer can request reconsideration, and that Health Canada is striving to exceed its review standards, the fact remains that there is an unmet need for Canadians living with ALS even with two authorized therapies already available. **We believe that the terminal nature of ALS, the swiftness of its progression, and the heterogeneity of the disease require that all proven ALS therapies be granted priority review without question.**

Our paper The Time is Now published in June 2021 articulates this position and recommends approaches for Canadians to access approved ALS therapies as quickly, affordably and equitably as possible. It is estimated that 80 per cent of people living with ALS will die within two to five years of their diagnosis, facing progressive paralysis the entire time. That is why the ALS community measures time not by days or months but by loss – loss of function and loss of life. **In the 300 days that it will take Relyvrio to move through Health Canada review, nearly 1,000 Canadians will die of ALS – that's equivalent to one-third of Canadians who are living with ALS right now.**

In the time since your letter was sent, we have learned that a new drug submission for Relyvrio is being made to the US Food and Drug Administration. While we believe that access to proven ALS therapies is a global need, we are concerned that the therapy may be approved in the US before Canada, despite the NDS being filed with Health Canada two months before the FDA.

I would welcome a meeting to talk further about the unmet need facing Canadians living with ALS and ways in which Health Canada can respond.

Sincerely,

Tammy Moore
CEO

cc. Dr. Supriya Sharma, Chief Medical Advisor

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Health Canada Santé Canada

September 8, 2021

Dear Tammy Moore:

Thank you for your email on August 31, 2021, regarding a priority review for Relyvrio (formerly referred to as AMX0035) for the treatment of ALS in Canada.

Health Canada understands the importance of accelerating drug reviews, especially in the case of diseases that progress quickly. We are making every possible effort to ensure the drug submission for Relyvrio is reviewed as quickly as possible.

As you know, the New Drug Submission filed to Health Canada for Relyvrio has entered review, but was not granted priority review status.

The Priority Review of Drug Submissions Policy expedites the review time for drugs entering the market from up to 300 days to up to 180 days.

This policy applies to a New Drug Submission (NDS) or a Supplemental New Drug Submission (S/NDS) for a serious, life-threatening or severely debilitating disease or condition for which there is substantial evidence of clinical effectiveness that the drug provides:

- effective treatment, prevention or diagnosis of a disease or condition **for which no drug is presently marketed in Canada**; or

- a significant increase in efficacy and/or significant decrease in risk **such that the overall benefit/risk profile is improved over existing therapies**, preventatives or diagnostic agents for a disease or condition that is not adequately managed by a drug marketed in Canada.

There are currently two drugs authorized by Health Canada for the treatment of ALS: Rilutek (riluzole), an oral tablet and Radicava (edavarone), an I.V. solution. RILUTEK was marketed in Canada in 2000 and may extend survival and/or time to tracheostomy in some patients with ALS, while RADICAVA was marketed in Canada in 2019 and is indicated to slow the loss of function in patients with ALS. As noted above, the existence of marketed treatments in Canada may affect whether a company is successful in obtaining a priority review of their submission.

It is worth noting that Health Canada's decision on priority review is subject to a Request for Reconsideration at the company's request.

Because Health Canada is unable to provide specific details about the priority review decision, or details of a submission under review, we recommend that you contact Amylyx Pharmaceuticals Inc. for any more specific questions you may have regarding the priority review decision.

Despite not being granted a priority review, please be assured that, in recognition of the severity of this disease, we are striving to exceed our review standards, while maintaining our commitment to approving products with sufficient data to support their quality, safety and efficacy. The ability to perform a robust review and issue a decision in a shorter timeframe will depend on a number of factors, including the strength of the evidence submitted, and the speed at which the drug sponsor provides responses to our requests for additional evidence or clarification.

In the interim, drugs that are not currently marketed in Canada may be requested via Health Canada's Special Access Program (SAP). The SAP provides access to non-marketed drugs for serious or life-threatening conditions when conventional therapies have failed, are unsuitable or are unavailable. Health Canada has been working to reduce the burden on SAP applicants and to secure access to products for patients as rapidly as possible.

The SAP will consider requests for access to Relyvrio as long as Amylyx Pharmaceuticals, Inc. is able and willing to supply the drug and until such time as the drug receives market authorization in Canada. At this time, Amylyx Pharmaceuticals, Inc. is reviewing every SAP request for Canadian patients on a case-by-case basis before providing access to the drug via the SAP, and a number of Canadian patients have been able to get access to Relyvrio through this route. To make a request, physicians may contact SAP at (613) 941-2108 or sapdrugs@hc-sc.gc.ca.

While we continue to modernize and improve our regulatory oversight of therapeutic products, we know that there is always room for improvement, and that is why we value input from groups like the ALS Society of Canada to ensure our regulatory processes are meeting the needs of Canadian patients.

I hope that this information is helpful.

Thank you again for writing.

Sincerely,

Alysha Croker

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