

Minister of Health



Ministre de la Santé

Ottawa, Canada K1A 0K9

DEC 17 2010

Durhane Wong-Reiger, Ph.D.
durhane@sympatico.ca

Dear Dr. Wong-Reiger:

Mr. David Sweet, Member of Parliament for Ancaster-Dundas-Flamborough-Westdale, has forwarded to me a copy of your correspondence of October 19, 2010, concerning a regulatory framework for orphan drugs. Dr. Colin Carrie, my Parliamentary Secretary, Ms. Irene Mathyssen, Member of Parliament for London-Fanshawe, Mr. Bill Siksay, Member of Parliament for Burnaby-Douglas, Mr. Phil McColeman, Member of Parliament for Brant, Mr. Don Davies, Member of Parliament for Vancouver Kingsway, the Honourable Laurie Hawn, Member of Parliament for Edmonton Centre, and Mr. Brent Rathgeber, Member of Parliament for Edmonton-St. Albert, have also written on your behalf. I regret the delay in responding.

The Government recognizes the difficulties faced by Canadians who are suffering from rare disorders, including limited and expensive treatment options and insufficient evidence of effectiveness when treatments are available. Health Canada is looking at ways to regulate drugs for rare diseases through its work to modernize the regulatory framework for drugs under the Food and Consumer Safety Action Plan.

On October 27, 2010, the Department began a series of technical discussions with stakeholders. These sessions will take place over a period of several months, and will allow us to test and validate proposed activities related to the access to, and regulation of, a product throughout its life cycle and identify areas that need further policy work. Treatment options for rare diseases are included as a part of these discussions.

Health Canada is at the exploratory stage with regard to an approach for treatments for rare diseases. The Department is also learning from, and consulting with, international partners about the best way to move forward. Our goal is to ensure that Canadians have the safest and most beneficial drugs for rare diseases approved for use as we consider options to modernize our regulations.

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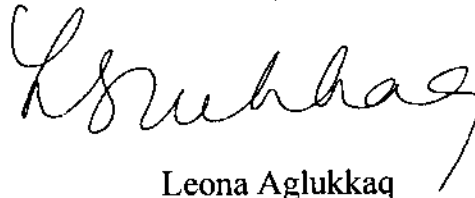
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Orphan drugs presently available in other jurisdictions may also be available through Health Canada's Special Access Programme on a case-by-case basis. The mandate of the Programme is to provide access to non-marketed drugs to practitioners treating patients with serious or life-threatening conditions when conventional therapies are unavailable, have failed, or are unsuitable. More information, including request forms, is available at <http://hc-sc.gc.ca/dhp-mps/acces/drugs-droques/index-eng.php>.

The federal government regulates the authorization process for pharmaceuticals in terms of their safety and efficacy, and provides significant funds to ensure the sustainability of the health care system. As the administration and delivery of health care, including drug coverage and the listing of treatments on formularies for reimbursement, is a provincial and territorial responsibility, you may wish to share your concerns with the provincial and territorial ministers of health. A list is available at <http://www.hc-sc.gc.ca/hcs-sss/delivery-prestation/ptrole/index-eng.php>.

I appreciate having had your concerns brought to my attention.

Sincerely,



Leona Aglukkaq

c.c. Mr. David Sweet, M.P.
Dr. Colin Carrie, M.P.
Ms. Irene Mathyssen, M.P.
Mr. Bill Siksay, M.P.
Mr. Phil McColeman, M.P.
Mr. Don Davies, M.P.
The Honourable Laurie Hawn, P.C., M.P.
Mr. Brent Rathgeber, Q.C., M.P.