
FAX COVER SHEET

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Date: July 29, 2013

To: Ian MacKay, Manager

Company/Department: Special Access Programme

Fax: 613 941-3194

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Re: Special access requests #30237 and #21463

From: Dr. Patricia Daly

Chief Medical Health Officer

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July 29, 2013

Ian MacKay
Manager
Special Access Programme
Therapeutic Products Directorate
Address Locator 3105A
Ottawa, Ontario K1A 0K9
Fax: 613 941-3194

Dear Mr. MacKay,

Re: Special Access Requests #30237 and #21463

As Chief Medical Health Officer and Vice-President of Public Health for Vancouver Coastal Health, I am writing to urge an expedited decision on the above requests related to patients exiting the Vancouver –based SALOME trial.

It has recently been brought to my attention that a patient exiting the SALOME trial, who did not have access to injectable diacetylmorphine upon exiting, has died of a heroin overdose. There can be no greater tragedy at the conclusion of any drug research trial than the death of a participant because they no longer had access to an effective intervention. I am gravely concerned that the failure of the Special Access Programme to allow patients exiting the SALOME trial access to injectable diacetylmorphine could result in further tragic outcomes.

I would remind you that participants in the SALOME trial are people who have failed currently available addiction treatment, including methadone treatment. I would further remind you that injectable diacetylmorphine is an effective, evidence-based treatment for those with opioid dependence who have failed conventional methadone treatment (NEJM 2009;361:777-86).

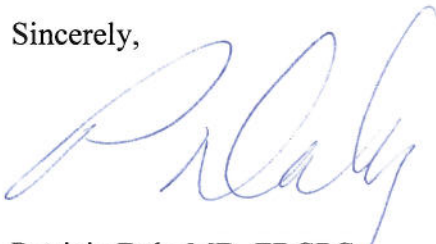
Vancouver Coastal Health is committed to providing primary care and addiction treatment for participants exiting the SALOME trial, as we provide the primary care services to the downtown eastside Vancouver community, where the study population for the trial resides. We have discussed the option of providing large-dose, oral hydromorphone to those exiting the trial, but this would be an off-label use of this drug. As there is currently no published scientific evidence to support this treatment option at the doses required, including evidence of benefits and risks, our addiction specialists will not prescribe it.

On the other hand, scientific evidence does exist to support the use of injectable diacetylmorphine in this population, but this treatment is not available in Canada. I would remind you of the purpose of the Special Access Programme, as articulated in your own materials:

“The Special Access Programme (SAP) allows practitioners to request access to drugs that are unavailable for sale in Canada. This access is limited to patients with serious or life-threatening conditions on a compassionate or emergency basis when conventional therapies have failed, are unsuitable, or are unavailable.”

SALOME participants have life-threatening addictions, have failed convention treatment and are in desperate need of access to a drug produced in Europe but not otherwise available in Canada. There is published evidence available in support of this treatment. I understand that the ability to import pharmaceutical diacetylmorphine requires approval from the Health Canada Office of Controlled Substances. Please work with your Health Canada colleagues in that office to expedite this request.

Sincerely,



Patricia Daly MD, FRCPC
Chief Medical Health Officer and Vice-President, Public Health
Vancouver Coastal Health

Cc: Dr. Scott MacDonald, Providence Crosstown Clinic