

No. 1 The Terrace PO Box 5013 Wellington 6145 New Zealand T+64 4 496 2000

1 8 FEB 2016

Mr Shane Le Brun

Email: Shane Le Brun <fyi-request-3510-5fba11c2@requests.fyi.org.nz>

Dear Mr Le Brun

Ref: H201600043 - Response to your request for official information

Thank you for your request of 1 January 2016 under the Official Information Act 1982 (the Act) for

- 1. A list of the conditions that have been granted off label approvals for the use of Sativex. I do not require a breakdown of number for the conditions as the small numbers would likely make individuals identifiable.
- 2. A list the details the symptoms prescribed for, e.g. Spasticity, or Nausea, and the underlying condition causing it, e.g. various forms of Epilepsy or Aids etc.

Attached is a table containing the information requested in questions 1 and 2. The underlying condition information requested in 2 is described in column 1.

I trust this information fulfils your request.

FMulio

Yours sincerely

Dr Don Mackie

Chief Medical Officer

Clinical Leadership, Protection and Regulation Directorate

Conditions that have been granted off- label approvals for the use of Sativex.	The symptoms of the condition listed in column 1 for which Sativex has been granted approval to prescribe
AIDS	cachexia and nausea
Amputee	severe neuropathic pain
Cancer/Palliative care	nausea and severe chronic pain
Cerebral Palsy, with spastic quadriplegia or refractory seizures	severe muscle spasms
Chronic restless legs with peripheral neuropathy	severe chronic pain and muscle spasms
Congenital Peroxisomal Disorder	persistent muscle spasms
Dravets Syndrome	muscle spasms and seizures
Encephalitis/Encephalopathy	severe neuropathic pain and refractory seizures
Fibromyalgia	severe neuropathic pain
Fredriechs Ataxia	muscle spasm and chronic pain
Intractable Epilepsy	muscle spasms and seizures
Motor Neurone Disease	severe muscle spasm and pain
Osteoarthritis	severe chronic pain
Pilocytic Astrocytoma	severe chronic pain
Sacral pressure ulcer and paraplegia	severe chronic pain and muscle spasms
Severe refractory headaches	severe chronic pain
Spina Bifida	severe chronic pain
Spinal injury	severe neuropathic pain
Status Epilepticus	severe muscle spasms and seizures
Surgical misadventure	severe chronic/neuropathic pain
Tetraplegia	muscle spasm and neuropathic pain
Tourettes Syndrome	severe muscle ticks and spasms
Traumatic brain injury	severe chronic pain
Tuberous sclerosis with severe intractable epilepsy	muscle spasms and seizures