

Medical Update Memo

April 19, 2005

Health Canada approves Sativex[®] for treatment of MS-related pain

Summary

On April 19, Health Canada approved Sativex[®], a cannabis-based drug for the treatment of MS-related pain. The drug consists of various extracts from the cannabis plant. It is administered via a spray into the mouth. The approval is based on a clinical trial which took place in Britain in 2002. Canada is the first country to approve Sativex. Bayer Canada will announce the cost and availability of the therapy shortly. The Multiple Sclerosis Society of Canada welcomes the approval of Sativex, which will provide people with MS and their physicians another choice in treating pain, which is a common symptom of the disease.

Details

Health Canada approval of Sativex on April 19 makes Canada the first country in the world in which the cannabis-based spray is available as a prescribed treatment for MS-related pain. Sativex is sprayed under the tongue or on the inside of the cheek from a dispenser that is programmed to deliver a pre-selected dosage. It is described as a whole marijuana plant extract. It includes two components of marijuana tetrahydrocannabinol (THC) and cannabidiol.

Health Canada has approved Sativex with conditions, under the Notice of Compliance with Conditions (NOC/c) policy. This authorization reflects the promising nature of the clinical evidence to be confirmed with further studies. Products approved under Health Canada's NOC/c policy, have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment for the approved use.

Health Canada approval was based on the results from a small, four-week clinical trial carried out in Great Britain by GW Pharmaceuticals, the company that developed Sativex. The study involved 66 people with MS at a research centre in Britain. Participants had central neuropathic pain because of MS. Half of the group received Sativex in a spray dispenser and the other half received a sham (placebo) spray in a similar dispenser.

The primary outcome measure was to measure the effectiveness of Sativex in relieving central neuropathic pain compared to placebo. Secondary measures included sleep disturbance, participants' perception of their condition at the end of treatment and other quality of life assessments.

Study results and possible mechanism of action

Participants in the Sativex group used fewer sprays per day than did the placebo group. In addition, individuals in the treated group reported they experienced pain relief, had less sleep disturbance and felt their condition had improved.

There were more side effects in the Sativex-treated group versus the placebo group. When combining data from this and several other phase three clinical trials (total of 166 participants), the most common side effect of Sativex was dizziness which occurred in 41.6% of treated participants versus 13% of participants in the placebo group. There was also more nausea in the treated group (10.2%) than in the placebo group (7.4%) and more fatigue in the treated group (11.4%) versus the placebo group (5.6%). Side effects tended to diminish overtime.

Cannabinoids is the name given to more than 60 related chemicals in the marijuana plant. Cannabinoids appear to bind to receptor molecules on the surface of neurons in the brain and spinal cord. Through a complex process, cannabinoids appear to prevent neurons from becoming overactive, which leads to the neuropathic pain sometimes experienced in MS. Neuropathic pain results directly from damage to the nerves.

A number of clinical trials have been carried out in the past five years to test the effectiveness and safety of marijuana as a treatment for MS pain and spasticity. Some studies used the smoked variety of marijuana, while others used extracts of the plant delivered in various ways. The outcome of the largest study, which looked at spasticity, was mixed in that while those on active treatment did not have an objective improvement as measured by a standardized scale, treated participants reported improvements in walking speed, another measure of spasticity,

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and symptoms of spasticity, muscle spasms, sleep and pain.

Pain as a symptom of MS

Up to 80 percent of people with MS report some type of pain. A recent study of pain at Dalhousie University involving 85 people with MS found that 53 percent of people with MS experienced pain during the study period and that 17 percent reported continuous pain. Of those reporting pain, 65 percent took medication to control pain, with 90 percent reporting that their pain could be controlled about half of the time. Study participants who reported pain had poorer overall mental health than people who were pain free or who had well-controlled pain. There is a wide variety of pain associated with MS from a range of causes: generalized pain, muscle spasms, trigeminal neuralgia (shooting pain in the face), painful sensations in the legs, feet and hands.

Background and status of marijuana as a therapy in Canada

Marijuana's role as a medication is complex and controversial. It was used as a medication in the nineteenth century but was outlawed in most western countries in the early to mid twentieth century. Recently in Canada, the federal government developed a medicinal marijuana program, which allows people who meet certain criteria to have permits to possess and grow marijuana. MS is among the conditions for which a permit can be applied. In some cases, Health Canada will provide marijuana to people who hold permits. Details about how to apply for permits are available at the Health Canada website: www.hc-sc.gc.ca; then click on Health Protection and then Medical Marijuana. Information is also available by calling the Health Canada Cannabis Medical Access Office toll-free: 1-866-337-7705 or 613 954-6540.

It is not known if the approval of Sativex will result in any changes to the Health Canada Marijuana Medical Access Program. One issue that has arisen from the Health Canada medical marijuana is that some physician organizations have advised their members not to prescribe marijuana because of the lack of information about optimum prescribing and potential legal issues.

Other cannabis-based drugs are Marinol® (dronabinol) and Cesamet® (nabilone). Both are synthetic versions of THC in tablet form. They are used primarily by people with cancer and AIDS to treat nausea related to certain treatments and to stimulate the appetite.

Multiple Sclerosis Society of Canada comment

The Multiple Sclerosis Society of Canada welcomes the approval of Sativex, which will pro-

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vide people with MS and their physicians another choice in treating pain, which is a common symptom of the disease. "Having available another way to manage pain is encouraging news," said Dr. William J. McIlroy, national medical advisor.

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