



Multiple  
Sclerosis  
Society of  
Canada

Société  
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## Medical Update Memo

July 23, 2004

### Bayer HealthCare submits cannabis spray for Health Canada approval

#### SUMMARY

Bayer HealthCare has applied to Health Canada for approval of a cannabis-based drug for the treatment of MS-related pain and spasticity. The drug, which is called Sativex, consists of various extracts from the cannabis plant. It is administered via a spray into the mouth. The application is based on clinical trials which took place in Britain in 2003. It typically takes up to two years for Health Canada to review a drug application. The MS Society is following the review process closely and will provide more information when it is available.

#### DETAILS

The Bayer HealthCare application to Health Canada for approval of the cannabis-based spray is based on the results of a clinical trial conducted in Great Britain last year which was reported in *The Lancet*, November 8, 2003. The British study involved 657 people with MS, the largest clinical trial of marijuana derivatives for the treatment of MS symptoms. For 13 weeks, participants received either cannabis oil, synthetic tetrahydrocannabinol (THC, the active ingredient in marijuana) or inactive placebo. Following the treatment period, those on active treatment had no objective improvement in muscle spasticity as measured by a standardized scale. However, treated participants reported improvements in walking speed, another measure of spasticity, and symptoms of spasticity, muscle spasms, sleep and pain.

#### Results

Data was obtained from 630 participants. There was no objective evidence of a treatment effect on muscle spasticity, the primary outcome of the study, using the standardized Ashworth scale. The Ashworth scale, a 5-point scale, measures restriction of movement in specific muscle groups and has been widely used in prior studies of spasticity and its treatment, however, it is known to measure only one aspect of spasticity. At the end of the study, physicians asked participants to rate their own sense of whether the agent they had taken had improved their symptoms. Significantly more participants taking either cannabis oil or THC reported subjective improvements in spasticity, spasms, sleep and pain, but not tremor or bladder symptoms.

Among secondary outcomes studied was the time it took to walk 10 metres. Walking times before and during treatment were obtained from 278 participants; there was a reduction in walking time by 12% in the group taking THC, compared to a reduction of 4% in both the cannabis oil and placebo groups. This

difference was statistically significant. There was no improvement on another mobility test.

There were serious adverse events in all three groups: 20 in the placebo group, 18 in the THC group and 12 in the cannabis oil group. More episodes of dizziness/ light-headedness, dry mouth, and gastrointestinal symptoms occurred in the treatment groups.

The investigators also noted there were fewer relapses in the treatment groups. Of the nine MS relapses that occurred during the study period, seven were in the placebo group and one each in the treatment groups. However, the study was not designed to investigate impact on relapses so no conclusions can be drawn from this finding.

### Legal Status in Canada

Health Canada regulations allow people with certain illnesses including MS to apply for permits to possess and/or grow marijuana for personal medical purposes or to designate another person to grow it for the person who has the permit. Health Canada is also conducting a pilot project involving the use of designated pharmacies to provide marijuana to permit holders.

All usages must be prescribed by physicians. Details about how to apply for permits are available at [www.hc-sc.gc.ca/hecs-sesc/ocma/index.htm](http://www.hc-sc.gc.ca/hecs-sesc/ocma/index.htm). Information is also available by calling the Health Canada Cannabis Medical Access Office toll-free: 1-866-337-7705 or 613 954-6540.

In July 2003, then federal Minister of Health Anne McLellan announced an interim policy to allow Health Canada to provide dried marijuana and/or marijuana seeds to individuals holding federal permits. This decision was in response to complaints by some permit holders that they were not able to access marijuana. The product and seeds will come from Prairie Plant Systems Inc., the company currently under contract with Health Canada to produce marijuana for clinical trials. Details about how to apply for dried marijuana and/or marijuana seeds are available at [www.hc-sc.gc.ca/hecs-sesc/ocma/index.htm](http://www.hc-sc.gc.ca/hecs-sesc/ocma/index.htm). Information is also available by calling the Health Canada Cannabis Medical Access Office toll-free: 1-866-337-7705 or 613 954-6540.

Some physician organizations have advised their members not to prescribe marijuana because of the lack of information about optimum prescribing and potential legal issues. It is not yet clear if these recommendations will change with respect to oral cannabis given the results of the *Lancet* study.

Individuals interested in the medical use of marijuana should speak to their own physicians or contact Health Canada.

**ASK MS Information System Code:**

**1.4.1.20.z**

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