

## **What Will Happen to Patients Who Drive After Taking Legalised Cannabinoid Sprays?**

George Michael's accident highlights the possible dangers of driving with cannabinoids in the blood. Under UK law this in itself is not an offence, however, if the driver is impaired due to the cannabinoids, then this creates an offence.

The UK has recently approved the use of a cannabinoid spray for the treatment of spasticity in patients with Multiple Sclerosis.

The Summary of Product Characteristics of this compound, which is the information that the regulatory authority approves to give to doctors, states in relation to Sativex and driving that *'Sativex may produce undesirable effects such as dizziness and somnolence which may impair judgement and performance of skilled tasks. Patients should not drive, operate machinery or engage in any hazardous activity if they are experiencing any significant CNS effects such as dizziness or somnolence. Patients should be aware that Sativex has been known to cause a few cases of loss of consciousness'*.

The Patient Information Leaflet which patients are given says that *'You must not drive or use machinery when you first start to take Sativex and until you are established on a stable daily dose. Sativex may cause you to feel sleepy or dizzy, which may impair your judgment and performance of skilled tasks. It has also rarely been reported to cause a brief loss of consciousness. Once you are more used to taking Sativex and your dose is stable, you should still not drive or use machinery if Sativex causes effects such as sleepiness or dizziness that could impair your ability to perform these tasks. If you are not sure, do not drive or operate machines'*.

[\*\*Dr Malcolm Vandenburg\*\*](#) whom has given many medico legal opinions involving patients whom have been prosecuted for driving with active and inactive cannabinoids in the system has given many opinions for the defence where patients have been prosecuted when their blood only contains inactive cannabinoids and there has been no evidence of impairment states that *'thus patients are not told not to drive and the Medicines and Healthcare products Regulatory Agency (MHRA) seem content with this warning. That is like telling people who have drunk alcohol that they are safe to drive unless they themselves feel impaired. How can that be right?*

The argument put forward is that the spray produces such a low concentration and clinical evidence suggests patients are unlikely to be effected, however, plasma levels in some patients reach concentrations which may impair driving skills and it is possible that they will not be aware of this.

The manufactures and MHRA also took into account the research evidence which did not show in many patients substantial impairment. However, some will be impaired. To leave it up to the patient is absurd.

[\*\*Dr Malcolm Vandenburg\*\*](#) wonders about the difference between legal Sativex and illegal smoking because as in the UK it is illegal to drive under the influence of substances such as illegal cannabis, it is interesting to know what position the courts will take if patients have accidents while their blood or urine shows they have cannabis in the body related to the prescription medicine.

If they are impaired, it is likely they could be prosecuted. It is interesting to postulate, but not useful as to what view the court will take.

How can it be legal to drive when impaired after smoking cannabis and not be illegal to drive after using prescription cannabis? The manufacturers and MHRA have created this paradox. They should have warned patients not to drive.

[Dr Malcolm VandenBurg](#) points out that the product licence holders and the MHRA obviously accept that Sativex may be psychoactive but wonders why this same warnings are not given in the Summary of Product Characteristics and the Patient Information Leaflet, they are clearly different. How can doctors be told something different from patients.

Despite the obvious psychoactivity of Sativex, the manufacturers and MHRA argue that they have taken the warning from other psychoactive medications such as the benzodiazepines where it is left up to the patient. However, although the warning to doctors is similar, the warning to patients is far more complicated. They thus acknowledge there is some danger. However, this could also be argued to be inadequate and our roads would certainly be safer if there was zero tolerance to both cannabis and benzodiazepines'.

**Dr Malcolm VandenBurg BSc MBBS MISMA FCP FFPM FRCP**

**T: 020 7435 9386 / 07850 049 134**

**Pinero House, 115a Harley Street, London W1G 6AR**

**[www.malcolmvandenborg.co.uk](http://www.malcolmvandenborg.co.uk)**

15 September 2010