# Cannabis Consumption and Motor Vehicle Collisions: Medico-Legal Implications and their Relevance to Sativex

by

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**Acute cannabis consumption and motor vehicle collision risk: systematic review of observational studies and meta-analysis**

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This meta-analysis confirms the statistical association of the presence of active metabolites of cannabis in drivers and an increased frequency of motor vehicle collisions. It shows the difficulty of extracting good, meaningful, scientific results from the plethora of publications on this subject, as from their initial search revealing 2,975 papers, they were only able to include nine in their studies.

What are the medico-legal implications of driving with active cannabinoids in the body? This review does not discuss the difficulties of relating the concentration of active 9-THC to impairment and accidents.

In the UK at present, cases often come to court with only the inactive carboxy metabolite being measured in the urine and without any impairment testing.

If either a per se limit or zero tolerance was established, active blood concentration of 9-THC will have to be measured in the blood, but this, often due to variability, does not predict effect. Laboratory testing shows greater impairment than road testing.

A study by Berghaus[1] et al showed that cannabis impaired skills which are important for driving and showed that in terms of blood levels, in which 50% of results were significantly deteriorated, this ranged from 6 ng/ml for tracking and 15 ng/ml for reaction time, simulator driving being 13 ng/ml.

THC impairment predominates in the absorption phase of the cannabis and frequent users reveal less impairment than infrequent consumers.

Drivers are more able to compensate their deficit than subjects who consume alcohol. The maximum high is achieved later than the maximum THC concentration.

In an effort to try to determine a concentration above which drivers are more likely than not to be impaired, a study by Khiabani[2] et al noted that the median blood concentration of apprehended drivers was 2.2 ng/ml with a very wide range of 0.3 to 45.3 ng/ml.

54% of the apprehended drivers were judged impaired. There was no difference in concentration of THC between regular and non-regular users, but regular users were less often judged to be impaired; 32% versus 55% and there was considerable overlap in the drug concentrations of impaired and non-impaired drivers, despite the significant relationship between the two.

Impaired drivers had a median concentration of 2.5 ng/ml with a range of 0.3 to 45.3 and non impaired drivers a medium of 1.9 ng/ml with a range of 0.32 to 24.8.

When drivers were grouped for THC concentration, there was a definite trend and correlation between increase in dose and proportion of drivers' judged impairment, but there was considerable overlap of the groups.

When people have tried to compare the THC concentration to produce a similar likelihood of impairment to an alcohol concentration over the legal limit, there has been no consensus of opinion.

Grotenhermen[3] et al in 2007 tried to define a limit for driving under the influence of cannabis and suggested that a concentration of between 7 and 10 ng/ml was equivalent to a blood alcohol concentration of 0.05%.

These papers have implications for Sativex, the recently approved cannabinoid tincture which has approval, I believe, in seven countries now for the treatment of patients with moderate to severe spasticity due to Multiple Sclerosis which is said to contain both 9-THC and cannabidiol, although it does contain many more cannabinoids. Due to the effectiveness of medicinal cannabis and indeed Sativex, this list of indications is likely to be considerably expanded to the benefit of patients and will probably include neuropathic pain, pain due to spinal problems and other severe pain.

The ability of Sativex users to drive is to my mind inadequately covered in the approved Summary of Product Characteristics presented by the product licence holders and approved in the UK by the MHRA which is indeed the lead regulatory body for European Sativex approvals. It states '*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 consciousnesse*s'.

Given that the measured concentrations of 9-THC with Sativex show a range of 0.97 to 9.34 ng/ml after a single dose administration of four sprays, it is likely that on chronic dosing if more sprays are used, the concentration will be considerably higher, (the SPC indicates up to 12 sprays being used, maybe more) even with the concentrations after four sprays, the range overlaps the concentration where effects are found and a possible per se limit. It is likely to be only a matter of time before a Sativex user has an accident with active 9-THC in the blood. The more successful Sativex is as a treatment, and the wider its indications are, the more likely this is to happen.

In this case, although approved by regulatory agencies, the warning is inadequate as with all other psychoactive medication the patients may not be aware if they are experiencing CNS effects as the effects on psychomotor function will be evident before both the patient is aware and they have more fully fledged symptomatology such as dizziness and somnolence. Indeed the manufacturers and the MHRA rely on the fact that this is a similar wording for other psychoactive substances which affect driving such as the benzodiazepines.

However, to my mind two wrongs don't make a right and I would strengthen the warnings for Sativex saying that users are advised not to drive and I would have the same warning for benzodiazepines. Hopefully meta-analysis such as the one currently published by the BMJ, will encourage the product licence holders and the regulatory agencies to take this view. The SPC for Sativex does not appear to have taken into consideration the research or medico-legal implications of cannabis.

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