

## APPENDIX I

# Cannabis and cannabis-based medicines: Potential benefits and risks to health

## **Patient information**

Cannabis or marijuana comes from the plant *Cannabis sativa* and has been used for centuries for the relief of symptoms from a variety of diseases. Concerns over the risks to health from cannabis use, particularly its effects on the brain, mean that its use is illegal in many countries. Nonetheless, cannabis is commonly used as a recreational drug and thousands of patients with AIDS, multiple sclerosis, chronic pain and a variety of other disabling diseases have tried and continue to use it in the firm belief that it makes their symptoms better.

It is important to recognise that no drug is absolutely safe. It is also important to distinguish between the recreational use of cannabis and its use as a medicine. Opinion on the value of cannabis as a medicine for a particular patient's symptoms or condition depends upon whether there is a need for a new medicine for that complaint, the chances and severity of side effects, and the amount of benefit it produces compared to existing treatments.

There is no doubt that new medicines are needed for the treatment of chronic pain and the relief of spasticity caused by multiple sclerosis. For other conditions for which cannabis has been suggested as a medicine, such as migraine, nausea and glaucoma, there are already very effective treatments. To be useful, cannabis has to be at least as good as and as safe as the medicines in current use.

Most people who use cannabis illicitly smoke dried cannabis flowers, leaves or extracts from the plant in a hand-rolled cigarette (or 'joint') or in a water pipe (or 'bong'). The effects of this are experienced within minutes, but the smoke contains many of the substances felt to be harmful in tobacco smoke. This causes concern that taking cannabis in this manner carries the same risks to the lungs as smoking tobacco and so is strongly discouraged.

The main active ingredient of cannabis is THC ( $\Delta^9$ -tetrahydrocannabinol). A synthetic form of this chemical known as dronabinol (Marinol<sup>®</sup>) and a related drug, known as nabilone, can be given in capsules by mouth. Extracts of cannabis have also been formulated for use as a mouth spray. Pharmaceutical companies have made and continue to make variations of THC with the aim of copying some of its desirable effects.

THC and cannabis extracts have well-recognised side effects. They can cause dizziness and clumsiness, affect mood, disturb thought processes and cause hallucinations; these are distressing but reversible. People differ in the doses they are able to tolerate and side effects are more likely to occur in people who are not regular users of cannabis.

The best tool for assessing the effectiveness of THC and cannabis extracts as a medicine is a clinical trial. In a clinical trial, the effects of the test drug are compared with those of an effective treatment or with a dummy-treatment known as a placebo. Clinical trials of dronabinol and nabilone indicate that these drugs can reduce nausea and vomiting caused by cancer chemotherapy, and they can be prescribed by doctors for this if conventional treatment has failed. Clinical trials of dronabinol and extracts of the cannabis plant in a spray formulation, known as Sativex<sup>®</sup>, provide some evidence to suggest that these drugs may provide some relief from chronic pain and spasticity, particularly in multiple sclerosis, but the results are not conclusive. Sativex<sup>®</sup> has recently been given provisional approval in Canada for the treatment of chronic pain associated with multiple sclerosis, and the UK Home Office has said that this drug can be imported into the UK for the treatment of individual patients on prescription from a doctor. Further clinical trials with these formulations for the treatment of the symptoms of multiple sclerosis and chronic pain are needed and indeed are already underway.

Major concerns arising from studies of the recreational use of cannabis are the risk of developing a long-term mental illness (known as psychosis), the risk of becoming dependent on the drug, and the possibility that it may lead on to other stronger drugs. Studies have shown more mental illness among people who have smoked cannabis regularly during adolescence than people from the same community who do not take cannabis. It is not clear from these reports that regular cannabis use actually causes mental illness but the association raises an alarm. Cannabis and cannabis-based medicines should not be given to adolescents or people with a history of mental illness unless there are clear benefits from such medicines in these groups and even then careful observation of these patients is necessary.

Studies of regular users of cannabis for recreational purposes suggest that around 10% of users show evidence of dependence. On the other hand, studies of the use of THC and cannabis extracts in multiple sclerosis for up to 12 months have not reported dependence on treatment as a problem, even though patients were allowed to vary the dose they use themselves to achieve the desired benefit. Similarly, there is no evidence that the use of THC and cannabis extracts in clinical trials leads to the use of stronger medicines, such as opiates.

In recent years, it has become clear that the body produces its own cannabis-like substances. The role these substances play in regulating body functions is gradually becoming clearer, and include the regulation of appetite and of factors which might influence heart disease and bone strength. This raises the interesting possibility in the near future of new drugs for the treatment of obesity, heart disease and osteoporosis. The benefits and safety of these drugs will be evaluated in studies designed according to well laid out regulatory guidelines for the development and approval of new medicines.

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This information is based on *Cannabis and cannabis-based medicines: Potential benefits and risks to health*, a working party report published by the Royal College of Physicians, London, in 2005.