Cannabis laws 'threaten validity of trials'

[LONDON] Clinical trials into the medical effects of cannabis could be in jeopardy unless current regulations are either changed or interpreted more flexibly, according to British scientists planning the trials.

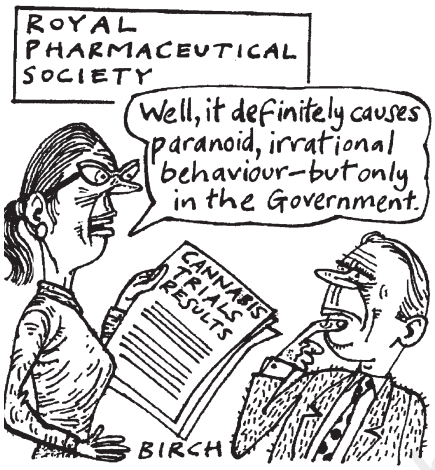
The outcome of the trials will help determine whether the government bows to calls to let doctors prescribe cannabis. The government last week rejected the latest such call, in a report from the House of Lords, saying that such a move depends on whether the medical benefits of cannabis are confirmed by scientific research.

The trials are planned under the aegis of the Royal Pharmaceutical Society in response to widespread — but primarily anecdotal — reports that cannabis is effective in pain relief, and that it helps to relieve the symptoms of multiple sclerosis (MS) sufferers.

Separate trials will attempt to establish and quantify these benefits. Protocols for the trials are being worked out by a group set up by the society. But whether the trials take place depends largely on the interpretation of requirements attached to awarding licences for cannabis research.

Applicants for a licence need to convince the Home Office that the drug will not be sold or used for any purpose other than the experiment. A further requirement is that the cannabis be administered, preferably in medicinal form, in the presence of a doctor or pharmacist in a specified location, usually a hospital or laboratory.

One consultant neurologist in London says the first condition is virtually impossible to meet, as most patients are already using the drug to alleviate their symptoms.



Roger Pertwee, reader in biomedical sciences at the University of Aberdeen, a former president of the International Cannabinoid Research Society and a member of the trials working group, highlights another difficulty. He says it is "essential" that patients on the MS trial can administer the drug at home, which current regulations do not allow.

Similarly, smoking the drug is known to be far more medically effective than the best available alternative of a tablet made by isolating the hydrocarbon cannabinoid ^{9}-THC, the main psychoactive compound of cannabis. But members of the working group acknowledge that the Home Office is unlikely to sanction large-scale trials involving cannabis being smoked.

Government officials acknowledge that the issue will not be easy to deal with under the current regulations. But they are confident that the trials will go ahead as planned, either in an outpatient arrangement or even at patients' homes.

"There are no statutory conditions to research licences other than the need for safe custody [of the drug], a finite time for the experiment, which should be conducted from a hospital, approval of the experiment by an ethics committee, and the keeping of records," says one official.

Last week's report from the House of Lords Select Committee on Science and Technology concludes that the legalization of medicinal cannabis will give a further boost to research. The report says that such a move should help remove the stigma felt by researchers of working with an illegal drug.

It adds that the legalization of medicinal cannabis will make it easier to get a research licence to study cannabis, and boost clinical trials by enabling cannabis users to come forward to take part. But professional bodies representing research scientists and pharmacists have reacted more cautiously.

The Royal Society says cannabis should remain banned until there is sufficient evidence of its medical benefits, irrespective of the impact on research.

The Medical Research Council and the Royal Pharmaceutical Society take a similar view, the latter claiming there is no direct evidence to suggest that research would benefit if prescribing cannabis were no longer a criminal offence. Tony Moffat, its chief scientist, says that, if anything, regular users will have less incentive to join a clinical trial if they can obtain the drug from their doctors.

The report from the House of Lords points out that there is little cannabis research at UK universities and pharmaceutical companies. The Home Office has issued only 27 research licences over the past 25 years, and four licences this year.

The report's main recommendation is to move cannabis from schedule 1 of the Misuse of Drugs Regulations 1985 to schedule 2. A drug in schedule 1 cannot be grown, used or prescribed, except under a research licence. Schedule 2 drugs can be used on the instructions of doctors and dentists. Drugs in both classes can be used for research.

Although cannabis is a schedule 1 drug, its main psychoactive ingredient, ^{9}-THC, is classified as a schedule 2 drug by the United Nations Convention on Psychotropic Substances, following advice from the World Health Organization that it has medical benefits.

Cannabis is the only schedule 1 drug of its kind that could be made legal for medicinal purposes by a change to UK law only. Any change to cannabis's remaining 60 constituent cannabinoids, which are all schedule 1 drugs, would need the assent of the UN convention. **Ehsan Masood**

India and Pakistan face more US sanctions

[NEW DELHI] **A week after partially lifting trade sanctions against India and Pakistan, the US administration has tightened controls on technology exports to organizations believed to be involved in nuclear missile and military programmes.**

Last Saturday (14 November), it named 250 entities in India and 90 in Pakistan for which US companies will require export licences to trade with. Most applications for licenses are expected to be denied.

Those singled out for sanctions in India include defence and atomic research agencies. Companies include the Fertilizer Corporation of India and Godrej & Boyce, which subcontracts from the Indian Space Research Organization, itself on the 'hit list'.

US officials in Delhi say the list will ease the burden on US exporters by "clarifying their responsibilities". The list is the largest release yet of US information on suspected nuclear and missiles proliferators to date.

The list is said to have been compiled by the Department of Defense, the State Department and the Central Intelligence Agency. It is divided into three categories: government agencies, government-affiliated and private companies, and military bodies.

The government's nuclear programme is denied all trade, but exports to government-affiliated bodies and private companies will be considered on a case-by-case basis. Military agencies will be denied export of items on a commerce commodity control list.

An Indian government spokesman described the move as "coercive and counterproductive". The Confederation of Indian Industries said publishing the list "would prove harmful to Indo-US business".

India plans to take the matter to the World Trade Organization (WTO). Commerce minister Ramakrishna Hegde said the US action was "inconsistent with WTO rules and regulations". **K. S. Jayaraman**