ACMD

Advisory Council on the Misuse of Drugs

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James Brokenshire MP
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17th January 2011

Dear Minister,

Re: Sativex

I am writing to provide you with the Advisory Council on the Misuse of Drugs' (ACMD) consideration of the cannabis based product "Sativex" following your correspondence to the ACMD on 22nd June 2010.

As you know, the Medicines and Healthcare products Regulatory Agency (MHRA) issued a marketing authorisation for Sativex last year for the add-on treatment for symptom improvement in patients with spasticity due to multiple sclerosis.

The ACMD re-considered the issue of scheduling of "Sativex" under the Misuse of Drugs Regulations 2001 (as amended) on 30th June 2010 to enable it to be available to patients via prescription under these regulations.

The ACMD previously considered this issue in 2003, following clinical trials that were being undertaken for cannabis based medicines for the treatment in limbs and muscular disability, predominantly in multiple sclerosis and chronic pain syndromes.

In 2003, the ACMD made its recommendation for Sativex to be placed in Schedule 4. The ACMD at its meeting on 30th June 2010 concluded that the 2003

recommendation remains appropriate. At this meeting the ACMD discussed, in detail, the relative merits for placing the new marketed drug in either Schedule 2 or 4. The ACMD concludes that Sativex has a low abuse potential and low risk of diversion. Therefore, the ACMD concludes that based on this assessment, “Sativex” should be scheduled as a Schedule 4, Part 1 substance.

The ACMD is conscious that the Home Office will need to take into account the UK’s obligations under the UN drug conventions, more particularly the Single Convention on Narcotic Drugs 1961 and its provisions relating to preparations. The ACMD is also aware that it will not be appropriate to refer to “Sativex”, which is a proprietary name, in any amendment to the misuse of drugs regulations, and that a suitable description of the relevant component(s) of “Sativex” will have to be scheduled (with appropriate consequential amendments to the Misuse of Drugs (Designation) Order 2001).

The ACMD would welcome being consulted further on any draft legislation.

The ACMD recognises the international, and trade dimensions of the appropriate scheduling. It would be the first cannabis-based medicine to receive approval in the UK and it is likely to be followed by similar products from the same or other companies. The licensing of Sativex in the UK may be followed by licensing in other areas of the European Union.

Yours sincerely,

Professor Les Iversen FRS