

ACMD

Advisory Council on the Misuse of Drugs

Chair: Professor Les Iversen CBE
Secretary: Rachel Fowler

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Jeremy Browne, Minister for Crime Prevention
Home Office
2 Marsham Street
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13 February 2013

Dear Minister,

Re: Definition of cannabis based medicine

I write further to my correspondence to James Brokenshire MP of 17 January 2011 in relation to the advice on the cannabis based medicine Sativex. In my previous correspondence, the Advisory Council on Misuse of Drugs (ACMD) reaffirmed its advice from 2003 that Sativex should be placed in Schedule 4 under the Misuse of Drugs Regulations 2001 (as amended). The ACMD further concluded that Sativex has a low abuse potential and low risk of diversion and therefore Schedule 4, Part 1 would be the most appropriate scheduling provision.

In October 2012 the Home Office presented to the ACMD a revised definition of cannabis based medicines, such as Sativex, under the Misuse of Drugs Regulations 2001. The ACMD gave detailed consideration to the the options and concludes that the most appropriate definition is:

“A liquid formulation–

(a) containing a botanical extract of Cannabis –

- (i) with a concentration of not more than 30 milligrammes of cannabidiol per millilitre, and not more than 30 milligrammes of delta-9-tetrahydrocannabinol per millilitre, and***
- (ii) where the ratio of cannabidiol to delta-9-tetrahydrocannabinol is between 0.7 and 1.3***

(b) which is dispensed through a metered dose pump as a mucosal mouth spray and

which was approved for marketing by the Medicines and Healthcare Products Regulatory Agency (MHRA)''

As Sativex has a low abuse potential and low risk of diversion, the ACMD also advises that it is not appropriate to apply Regulation 27 of the Misuse of Drugs Regulations 2001. The ACMD does not consider the witnessing requirements set out in Regulation 27 necessary for Sativex.

The ACMD is conscious of the UK's obligations under the United Nations Single Convention on Narcotic Drugs 1961. The ACMD is satisfied with the proposal to expand Regulation 22 to include a new sub paragraph (5) requiring anyone who acquires or disposes of drugs in Schedule 3 and 4 (including Sativex) to keep records of such acquisition or disposal. These measures will ensure that UK complies with its international obligations under the UN *Single Convention on Narcotic Drugs 1961 (Article 34 (b))*.

It is important to make clear that the ACMD considers that cannabis based medicines (as tightly defined above) are distinct from herbal cannabis. The definition above delineates cannabis based medicines, where the active ingredients are specific and tightly controlled, from herbal cannabis, which remains a Schedule 1 drug.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Les Iversen', written in a cursive style.

Professor Les Iversen FRS CBE

Cc: Anna Soubry, Parliamentary Under Secretary of State for Health