Title: Scheduling of cannabis-based medicine "Sativex"	**Impact Assessment (IA)**
IA No:	**Date:** 22/05/2012
Lead department or agency: Home Office	**Stage:** Final
	Source of intervention: Domestic
Other departments or agencies:	**Type of measure:** Secondary legislation
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Summary: Intervention and Options

RPC Opinion: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
£0	£0	£0	No	NA

What is the problem under consideration? Why is government intervention necessary?

"Sativex" is a cannabis-based medicine developed for the treatment of spasticity due to multiple sclerosis. The drug is currently available for use in healthcare under a Home Office general licence issued in 2006 during the development of the drug, and outside the regulatory framework governing the use of all controlled drugs in the UK. Sativex received marketing authorisation in the UK in 2010 and the Advisory Council on the Misuse of Drugs , the Government's independent expert advisors on drug issues, has recommended that the drug is scheduled under the regulatory framework - the Misuse of Drugs Regulations 2001 - to ensure continued ready access for use in healthcare whilst preventing diversion and misuse.

What are the policy objectives and the intended effects?

The policy objective is to recognise "Sativex" as a medicine by rescheduling in common and for consistency with other controlled drugs that are also medicines. this will ensure "Sativex" continues to be available for use in healthcare under the regulatory framework governing all controlled drugs rather than under the Home Office licence issued during the development of the drug. The intended effect is ready access for healthcare under an effective regulatory regime that prevents diversion and misuse.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: No change
This option mantains the status quo - the availability of Sativex under the Home Office General Licence.

Option 2: Scheduling of Sativex in Schedule 4 Part 1 to the Misuse of Drugs Regulations 2001.
This option brings Sativex in line with all other controlled drugs and ensures availability of the drug is governed by the regulatory framework governing the use of controlled drugs that are medicines in healthcare.

Option 2 is the preferred option.

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** Month/Year

Does implementation go beyond minimum EU requirements?			Yes		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: ..... Date: 13-03-13

Summary: Analysis & Evidence

Policy Option 2

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				**0**

Description and scale of key monetised costs by 'main affected groups'

N/A

Other key non-monetised costs by 'main affected groups'

There are no expected costs of this proposal.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				**0**

Description and scale of key monetised benefits by 'main affected groups'

N/A

Other key non-monetised benefits by 'main affected groups'

There are no expected benefits of this proposal other than an increase in consitency and clarity, neither of which are expected to involve significant monetary value.

Key assumptions/sensitivities/risks — **Discount rate (%)**

Moving Sativex from schedule 1 to 4 may lead to an increase in the amount of the drug prescribed, especially with changes that have recently been implemented around independent prescribing. However, the availability of the drug will be determined by Primary Care Trusts based on national guidance issued by NICE. There is no obligation on PCTs to make the drug available under the 2001 Regulations.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs:	**Benefits:**	**Net:** 0	No	NA

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

In June 1998 GW Pharmaceutical made an application for, and was granted, a Schedule 1 Home Office licence for *'research or other special purpose'* for the production of cannabis for research. This was in response to calls by multiple sclerosis sufferers and representative bodies who had long argued that cannabis had therapeutic properties. Later that year the House of Lords Science and Technology Committee published a report recommending that clinical trials of cannabis-based medicines be carried out as a matter of urgency. In response, the then Government undertook to amend controlled drug legislation, in consultation with the Advisory Council on the Misuse of Drugs (ACMD), the independent body which advises Government on drug issues, to enable cannabis-based medicines approved by the Medicines Healthcare Regulatory products Agency (MHRA) to be made available on prescription under regulation rather than a licence.

"Sativex" is a cannabis-based oral spray developed by GW Pharmaceuticals with its partner Bayer Schering Healthcare. Cannabis is a Class B drug under the Misuse of Drugs Act 1971 (the 1971 Act), and a Schedule 1 drug under the Misuse of Drugs Regulations 2001 (the 2001 Regulations). This means that it is unlawful to produce, supply or possess cannabis or cannabis-based products unless under lawful authority. Pursuant to section 7(4) of the 1971 Act, cannabis is also a designated drug which means that it cannot be lawfully possessed, produced, administered, compounded or supplied except for the purposes of *'research or other special purposes'* under a licence issued by the Home Secretary. The cannabis based medicine "Sativex" is treated in the same way as cannabis which means that any dealing with the drug had to be in accordance with a Home Office licence

In 2006, during the development of "Sativex", and pending marketing authorisation, the Home Office issued a licence to enable doctors, at their own risk, to privately prescribe, pharmacists to possess and dispense, and named patients who have been prescribed "Sativex" to possess the drug under a clinical trial (clinical trials have ended). Following the clinical trials, the MHRA, the competent body on efficacy and safety of medicinal products, issued a marketing authorisation for "Sativex", specifically as an add-on treatment for symptom improvement in patients with spasticity due to multiple sclerosis in June 2010.

Following the grant of the marketing authorisation and at the request of the Home Office, the ACMD considered the issue of scheduling of "Sativex" under the 2001 Regulations to enable it to be available to patients via prescription under these regulations rather than under the open general licence and to remove applicability of requirements as a result of it being subject to provisions applicable to Schedule 1 drugs. The ACMD concluded that "Sativex" has a low abuse potential and low risk of diversion. Therefore, the ACMD has recommended that based on this assessment, "Sativex" should be scheduled as a Schedule 4, Part 1 substance under the 2001 Regulations.

The proposal to schedule "Sativex" will ensure that the drug continues to be available for use in healthcare but under the regulatory framework governing the use of all controlled drugs that are medicines in the UK whilst at the same time ensuring any risks of diversion and misuse are minimised.

The manufacturers of "Sativex" have confirmed that the scheduling of "Sativex" will have no impact on its production or availability in the UK. The only change following this proposal is that the drugs will be available under the regulatory framework rather than under a licence.

A.2 Groups Affected

Groups affected by this policy are: patients, pharmacists, practitioners, pharmaceutical wholesalers, manufacturers and clinicians.

A.3 Consultation

Within Government

The Home Office has consulted the Department of Health

Public Consultation

The Home Office has consulted the Advisory Council on the Misuse of Drugs and GW Pharmaceuticals, the manufacturers of "Sativex" extensively.

B. Rationale

The rationale for this policy is that "Sativex" should be brought in line with all other controlled drugs that are medicines and that its availability should be subject to an effective regulatory regime which enables availability for healthcare purposes whilst preventing diversion and misuse. By placing "Sativex" in Schedule 4 Part 1 a distinction is also made between "Sativex" and cannabis in its raw form which continues to remain a Schedule 1 drug under the 2001 Regulations.

C. Objectives

The objective is to ensure continued availability of "Sativex" for use in healthcare under the regulatory framework governing controlled drugs, thus providing ready and wide access to the drug.

D. Options

Option 1: Make no changes (do nothing).

This option maintains the status quo and would mean "Sativex" will continue to remain outside the regulatory framework governing all controlled drugs that are medicines but available under the Home Office licence, originally issued to enable clinical trials to take place in 2006. This option is not supported by ACMD advice or by Government.

Option 2: Scheduling of "Sativex" as a Schedule 4 Part I drug under the 2001 Regulations.

This option will ensure that future availability of "Sativex"; its prescribing, dispensing and possession will take place under the regulatory framework governing the use of controlled drugs in healthcare – the Misuse of Drugs Regulations 2001. It will align "Sativex" with drugs that pose similar harms when misused under the regulatory framework and provide clarity to prescribers, dispensers and patients on the specific regulatory requirements applicable to the drug.

Option 2 is the preferred option and is supported by ACMD advice.

E. Appraisal (Costs and Benefits)

GENERAL ASSUMPTIONS & DATA

OPTION 2 – to schedule "Sativex" under the Misuse of Drugs Regulations 2001 as a Schedule 4 Part I controlled drug

There are no expected costs or benefits associated with scheduling "Sativex" under the Misuse of Drugs Regulations 2001. The drug will continue to be available to healthcare in the same way as it is under the general Home Office licence (except for the additional recording requirements under the 1961 UN Convention on Psychotropic substances). The only difference is that the

drug will be available under the regulatory framework governing all controlled drugs but without additional safe custody requirements.

It is unlikely that there will be any implications in terms of direct administrative burdens, further opportunity for misuse or any other effects. It is not expected that any change in the availability of the drug or quantity prescribed will result from the legal changes because neither patients nor prescribers will face any real changes (see Risks section below).

By bringing Sativex in line with other controlled drugs, there is a consistency benefit and a clarity benefit to clinicians. However these benefits are not expected to have any significant monetary value.

F. Risks

OPTION 1 – Do nothing

No clarity on requirements applicable to Sativex

The regulatory framework for controlled drugs is well established and understood by healthcare professionals. The schedule in which a drug is listed determines the requirements applicable to the drug. As Sativex is currently available under a Home Office licence, reference needs to be made to the licence to establish the requirements applicable to the drug. This does not provide the same clarity available under the regulatory framework and there is always a risk that the terms of the licence may be ignored or misinterpreted.

Reluctance to prescribe Sativex as a result of being a Schedule 1 CD

Sativex is derived from cannabis and therefore a schedule 1 drug under the regulatory framework. Schedule 1 is reserved for drugs with no medicinal. As a result there is always the possibility that prescribers may feel reluctant to prescribe the drug to patients.

OPTION 2 – to schedule "Sativex" under the Misuse of Drugs Regulations 2001 as a Schedule 4 Part I controlled drug

Moving Sativex from schedule 1 to 4 may lead to an increase in the amount of the drug prescribed, especially with changes that have recently been implemented around independent prescribing. However, the availability of the drug will be determined by Primary Care Trusts based on national guidance issued by NICE. There is no obligation on PCTs or Commissioning Boards to make the drug available under the 2001 Regulations. Sativex is unlikely to be used as substitute for other drugs due to the high costs involved. There are many other drugs for pain relief and it is expected, as is currently the case, that Sativex will only be prescribed where traditional routes for pain management have been explored but not worked for specific patients.

G. Enforcement

Enforcement of the proposed legislation will be undertaken by the Police Service, Health Regulatory Bodies, Accountable Officers and other relevant agencies within the health sector.

H. Summary and Recommendations

The table below outlines the costs and benefits of the proposed changes.

Table H.1 Costs and Benefits

Option	Costs	Benefits

2	£0 (PV over 10 years)	£0 (PV over 10 years)

The net present values of both Options 1 and 2 are zero. Option 2 is the preferred option. This option would ensure the availability of "Sativex" as a medicine for use in healthcare is regulated by the regulatory framework governing all controlled drugs in the UK. This would provide clarity to clinicians on the requirements applicable to the drug and consistency with the regulation of other controlled drugs.

I. Implementation

The Government plans to implement these changes on **10th April 2013**.

J. Monitoring and Evaluation

The effectiveness of the new regime would be monitored by the Government through the regulatory framework governing medicines and controlled drugs, and also through the oversight of Accountable Officers and the healthcare regulatory bodies in England and the Devolved Administrations.

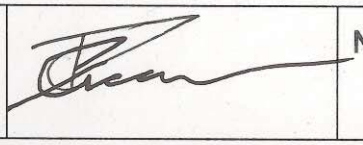
K. Feedback

Feedback will be sought from the manufacturers and medical prescribers of Sativex, Accountable Officers and health regulatory bodies in England and the Devolved Administrations.

Annex E

Home Office

Name of Policy/Guidance/Operational Activity
Legislative changes to schedule the cannabis-based medicine "Sativex" under the Misuse of Drugs Regulations 2001 *(the 2001 Regulations)*. "Sativex" is currently available for use in healthcare under a Home Office General License which enables doctors at their own risk to prescribe, pharmacists to possess and dispense, and named patients to possess the drug. The objective is to enable the continued availability of "Sativex" for use in healthcare under the regulatory framework governing the availability of controlled drugs that are also medicines – the 2001 Regulations – and to remove application of the "designation" requirements currently applicable to "Sativex", as a cannabis-based medicine, as it now has an established use as a medicine. When implemented the changes will ensure that the continued availability of "Sativex" for use in healthcare will be governed by the 2001 Regulations, which will determine the specific regulatory requirements applicable to "Sativex" as a Schedule 4 Part I drug.
Summary of the evidence considered in demonstrating due regard to the Public Sector Equality Duty.
The legislative change is a simple administrative change and follows the grant of a Marketing Authorisation by the Medicines and Healthcare products Regulatory Agency (MHRA) for "Sativex" for the treatment of patients with spasticity due to multiple sclerosis in 2010. The Advisory Council on the Misuse of Drugs (ACMD) has been consulted as statutorily required and is supportive of the legislative change. The ACMD did not identify any equality issues in their consideration. The ACMD advice is available at; http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/sativex-letter http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/advice-sativex The MHRA Marketing Authorisation for "Sativex" is available at; http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con084961.pdf

SCS sign off		**Name/Title**	Daniel Greaves Head of Drugs and Alcohol

I have read the available evidence and I am satisfied that this demonstrates compliance, where relevant, with Section 149 of the Equality Act and that due regard has been made to the need to: eliminate unlawful discrimination; advance equality of opportunity; and foster good relations.

Directorate/Unit	Crime Directorate/ Drugs and Alcohol Unit	**Lead contact**	Desmond Niimoi Drugs and Alcohol Unit X3533
Date 8/3/2013		**Review Date**	