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Department of
Health

An Roinn Sláinte
Máinnstríe O Poustie



Llywodraeth Cymru
Welsh Government

Tuesday 20th November 2018
Gateway Publications clearance: 08652

Dear Colleagues

Supplementary information on cannabis-based products for medicinal use

Following the letter issued on the 31st of October 2018, this supplementary letter provides further guidance to clinicians and organisations following the re-scheduling of cannabis-based products for medicinal use on November 1st 2018.

Clinical Guidance

We have been asked to clarify the status of the clinical guidance issued.

As highlighted previously, the National Institute for Health and Care Excellence (NICE) has been asked by the Department of Health and Social Care to produce a clinical guideline on the prescribing of cannabis-based products for medicinal use in humans. This guideline is expected by October 2019 at the latest.

The interim clinical guidance published by the British Paediatric Neurology Association (BPNA) on the use of cannabis-based products for medicinal use in children and young people with epilepsy and the Royal College of Physicians (RCP) guidance around prescribing of cannabis-based products for medicinal use in chemotherapy induced nausea and vomiting, chronic pain and pain in palliative care patients is based on the best available clinical evidence. NHS England have also asked the Association of British Neurologists (ABN) to provide interim guidance on the use of cannabis-based products for medicinal use in adult neurological conditions, including Multiple Sclerosis (MS).

Whilst this interim guidance is available to support specialist doctors on the Specialist Register of the General Medical Council (GMC) in deciding whether to prescribe cannabis-based products for medicinal use in a limited number of conditions, this does not remove or replace

the clinical discretion of the prescriber in accordance with their professional duties. We expect clinicians to work with their individual patients or their carers (where appropriate) to agree the best treatment, taking into account the clinical evidence base, GMC prescribing guidance on licensed, off label and unlicensed medicines, and local medicines governance systems. This is in line with normal clinical practice.

A set of clinical frequently asked questions (FAQs) is currently being prepared to provide further support to prescribers; once available these will be published [here](#). In the meantime, clinicians should discuss any queries around prescriptions with their local hospital Chief Pharmacist/Director of Pharmacy in the first instance.

Synthetic Cannabinoids

Cannabis-based products for medicinal use can be divided into those that are naturally occurring in the cannabis plant and those that are synthetic. A summary of naturally occurring products are provided in annex 1.

We would also like to provide further clarification in relation to synthetic cannabinoids for medicinal use. This clarification is intended to help clinicians understand the distinctions between the different types of synthetic cannabinoids and to raise awareness that two synthetic cannabinoids (Dronabinol and Nabilone) remain available for prescribing and have not been affected by the recent legislative change.

There are three main groups of chemical compounds that fall within the broad category of 'synthetic cannabinoids'.

1. Synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC) e.g. Dronabinol.
2. Synthetic compounds structurally *related* to naturally occurring cannabinoids that have been developed to mimic naturally occurring cannabinoids such as THC e.g. Nabilone.
3. Synthetic compounds not structurally related to naturally occurring cannabinoids but which bind to cannabinoid receptors in the body.

With respect to group 1 compounds, Dronabinol has been developed as a medicinal product. In addition, in group 2, Nabilone has also been developed for medicinal use and is available as a licensed medicinal product. See Annex 2 for further details.

Group 3 synthetic compounds not structurally related to naturally- occurring cannabinoids but which bind to cannabinoid receptors in the body are not available as licensed medicinal products. Many of the compounds in group 3 have frequently been found in illicit street products referred to by the street names of Spice and Black Mamba, and are predominantly new psychoactive substances (NPS). There is clear evidence of significant harm and several deaths associated with their illicit use.

The Advisory Council on the Misuse of Drugs (ACMD) has particular concerns with compounds falling within group 3 and others within group 2, with the exception of Nabilone, and is of the view that further research into this complex group of diverse substances is important, given the associated potency and harms. The ACMD stated that they needed

further time to consider and consult on the unintended consequences of the potential rescheduling of these products. Therefore, all synthetic cannabinoid compounds, unless authorised for medicinal use, will remain in Schedule 1 of the Misuse of Drugs Regulations 2001 (and Misuse of Drugs (Northern Ireland) Regulations 2002) at least until the full ACMD review is concluded; this is due to be published by July 2019. Consideration may then be given as to whether to re-schedule any further synthetic cannabinoid compounds for medicinal use.

As it currently stands: Compounds in group 1, such as Dronabinol, can lawfully be prescribed. Only compounds in group 2 that have been rescheduled individually under the Misuse of Drugs Regulations 2001 can be prescribed e.g. Nabilone. None of the synthetic compounds in group 3 are available for prescribing.

Further information can be found [here](#)¹ and on the current classifications of cannabis products for medicinal use in the annexes to this letter.

This letter has been agreed by Chief Medical Officers and Chief Pharmaceutical Officers across the United Kingdom.

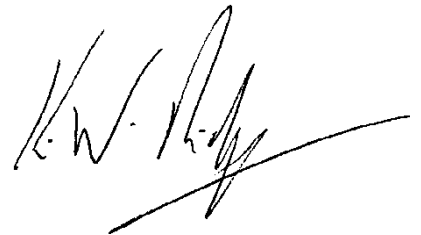
Yours sincerely,



Professor Dame Sally C Davies
Chief Medical Officer, England



Professor Stephen Powis
National Medical Director
NHS England



Dr Keith Ridge CBE
Chief Pharmaceutical
Officer
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Dr Frank Atherton
Chief Medical Officer/Medical Director
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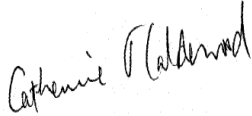
¹ <https://www.england.nhs.uk/medicines/support-for-prescribers/cannabis-based-products-for-medicinal-use/>
<https://gov.wales/docs/dhss/publications/whc2018-039en.pdf>
<https://www.health-ni.gov.uk/sites/default/files/publications/health/hss-md-28-2018.pdf>
[https://www.sehd.scot.nhs.uk/cmo/CMO\(2018\)15.pdf](https://www.sehd.scot.nhs.uk/cmo/CMO(2018)15.pdf)



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Annex 1

Summary of Naturally Occurring Cannabis-Based Products for Medicinal Use

Product	Constituents	Licensing	Indication	Controlled Drug Status	Which clinicians can prescribe?	Commissioning arrangements in England only ²
Cannabis-based products for medicinal use as defined by the change in regulations on 1st November 2018						
Cannabis-based products for medicinal use³ e.g. Tilray and Bedrocan products that were supplied under a Home Office (HO) licence.	<p>A range of preparations containing delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) with differing percentages of the active constituents.</p> <p>The product to be specified by brand/supplier; cannabis strain and content of THC/CBD (and ratio of THC/CBD where relevant), as appropriate.</p>	<p>Unlicensed specials</p> <p>Suppliers should comply with MHRA guidance and Good Manufacturing Practice standards.</p>	<p>Available on a named patient basis for indications where there is clear published evidence of benefit or UK Guidelines and in patients where there is a clinical need which cannot be met by a licensed medicine and where established treatment options have been exhausted.</p>	Schedule 2	<p>Specialist doctors on the GMC specialist register only can take the decision to prescribe.</p>	<p>Commissioning will depend on the indication that these products are prescribed for.</p> <p>Trusts will need to pick up the costs for named patients until normal commissioning processes can be defined.</p>
Cannabis-based products already available for medicinal use in the UK prior to 1st November 2018						
Epidiolex® oral solution	<p>Cannabidiol (CBD) isolated in pure form from Cannabis.</p>	Unlicensed in the UK.	<p>Approved by the US Food and Drug Administration (FDA) for Lennox-Gastaut Syndrome or Dravet Syndrome in patients 2 years of age and older.</p>	Not a controlled drug	<p>No restrictions on prescribing however likely to be specialist prescribing due to the nature of the proposed indications.</p>	<p>Lennox-Gastaut Syndrome and Dravet Syndrome is commissioned by NHS England Specialised Commissioning. Not routinely commissioned currently but this will be tariff excluded from April 2019 subject to a consultation.</p>

² Arrangements for the routine availability of medicines will differ in Scotland, Wales and Northern Ireland and clinicians should confirm specific arrangements in line with local protocols.

³ Note: Other cannabis-based products are on the market, often sold as food supplements. There is no assurance they have been manufactured to Good Manufacturing Practice standards using pharmaceutical grade ingredients or that they have consistent levels of ingredients between batches. These products should not be prescribed.

			Currently going through licensing in Europe. The marketing authorisation for the UK may further define who should prescribe.		Currently unlicensed so accessed on a named patient basis.	Currently going through normal commissioning processes and a NICE Technology Appraisal due for publication in November 2019. Early Access Programme available – speak to your local hospital Chief Pharmacist.
Sativex® (nabiximols) oromucosal spray	Extracts from two strains of cannabis with standardised content of the active constituents delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).	Licensed	Symptom improvement in adult patients with moderate to severe spasticity due to Multiple Sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.	Schedule 4	Must be initiated and supervised by a doctor with specialist expertise in treating MS patients as defined by the Marketing Authorisation.	Sativex® falls under the commissioning responsibility of Clinical Commissioning Groups (CCGs). However, it is currently not recommended by NICE.

Annex 2

Summary of Synthetic Cannabis-Based Products for Medicinal Use

Product	Constituents	Licensing	Indication	Controlled Drug Status	Which clinicians can prescribe?	Commissioning arrangements in England only ⁴
Synthetic cannabis-based products already available for medicinal use in the UK prior to 1st November 2018						
Dronabinol capsule	Synthetic structurally-identical form of delta-9-tetrahydrocannabinol (THC) (Group 1).	Unlicensed in the UK.	It has been approved by the US Food and Drug Administration (FDA) to treat loss of appetite in people with AIDS, and to treat severe nausea and vomiting caused by cancer chemotherapy in patients with inadequate response to conventional antiemetic treatments.	Schedule 2	No restrictions on prescribing. Unlicensed so accessed on a named patient basis.	Chemotherapy and HIV services are commissioned by NHS England. This would be in tariff but as an unlicensed medicine it would not be routinely commissioned. Trusts would pick up costs.
Nabilone capsule	Synthetic non-natural cannabinoid that mimics delta-9-tetrahydrocannabinol (THC) (Group 2).	Licensed	Nausea and vomiting caused by chemotherapy, unresponsive to conventional antiemetics.	Schedule 2	No restrictions on prescribing. Summary of product characteristics states: Preferably administered in a Hospital setting, under close supervision. GP's may prescribe once initiated.	NHS England is responsible for commissioning chemotherapy and associated supportive drugs if given as part of a chemotherapy regimen. If used outside an agreed regimen it is considered in tariff.

⁴ Arrangements for the routine availability of medicines will differ in Scotland, Wales and Northern Ireland and clinicians should confirm specific arrangements in line with local protocols.