



Department  
of Health &  
Social Care



Wednesday 31<sup>st</sup> October 2018  
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Dear Colleagues

### **Cannabis-based products for medicinal use**

The Government has announced plans to reschedule certain cannabis-based products for medicinal use, and has laid regulations in Parliament to that effect. Subject to annulment by either House of Parliament, those regulations will come into force on 1<sup>st</sup> November 2018. This letter provides support and guidance to clinicians following the re-scheduling. In particular, this letter sets out our expectations of what this regulatory change will mean in practice for clinicians working in the NHS and in private practice in England.

#### **Background**

As you may be aware, in June 2018 the Home Office launched a review into the scheduling of cannabis and cannabis-based products for medicinal purposes. Part 1 of the review from Professor Dame Sally Davies, Chief Medical Officer (CMO) for England and Chief Medical Advisor to the UK Government, assessed the therapeutic and medicinal benefits of cannabis-based products for medicinal use in humans on prescription, and found that there is conclusive evidence of therapeutic benefit for certain medical conditions, and reasonable evidence in several other medical conditions. The CMO recommended that the whole class of cannabis-based products for medicinal use in humans be moved out of Schedule 1 of the [Misuse of Drugs Regulations 2001 \(MDR\)](#)<sup>1</sup>.

The Advisory Council on the Misuse of Drugs (ACMD) thereafter concluded the first aspect of part 2 of the review<sup>2</sup>. It also recommended that “*cannabis-derived medicinal products of the appropriate standard*” be moved out of Schedule 1 and, subject to further refinement of the definition of cannabis-based products for medicinal use, into Schedule 2. Synthetic cannabinoids were specifically excluded from this and reserved for further consideration.

Moving cannabis-based products for medicinal use to Schedule 2 will mean those cannabis-based products can be prescribed medicinally where there is an unmet clinical need.

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<sup>1</sup> <https://www.gov.uk/government/publications/cannabis-scheduling-review-part-1>

<sup>2</sup> The final aspect of this review will be concluded by the summer of 2019.

In light of the above, the Government has decided to lay regulations which will move cannabis-based products for medicinal use out of Schedule 1 and into Schedule 2 of the MDR, with the exception of synthetic cannabinoids<sup>3</sup>. Subject to annulment by either House of Parliament, those regulations will come into force on 1<sup>st</sup> November 2018.

### **Prescribing cannabis-based products for medicinal use.**

The Government has [defined a cannabis-based product](#) for medicinal use in humans as:

“a preparation or other product, other than one to which paragraph 5 of part 1 of Schedule 4 applies, which—

- (a) Is or contains cannabis, cannabis resin, cannabidiol or a cannabidiol derivative (not being dronabinol or its stereoisomers)<sup>3</sup>;
- (b) Is produced for medicinal use in humans; and—
- (c) is—
  - (i) a medicinal product, or
  - (ii) a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product;”

Under the proposed new regime, all cannabis-based products for medicinal use apart from Sativex® (listed in Schedule 4 of the MDR and which has a market authorisation) would be **unlicensed medicines**. Further information on licensing of medicinal products is provided in the **Annex** to this letter.

Due to the limited evidence base and their unlicensed nature, the Government has chosen to restrict the decision to prescribe cannabis-based products for medicinal use to only those clinicians listed on the Specialist Register of the General Medical Council. This restriction has been set out in regulations.

As with any unlicensed medicines or "specials", the prescribing of such products must be on a "named patient" basis. It is therefore expected that rigorous and auditable safeguards around prescribing of an unlicensed product will be followed, alongside existing protocols on controlled drugs.

NHS England expects that cannabis-based products for medicinal use should only be prescribed 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. In addition, a Specialist doctor on the General Medical Council Specialist Register should only make the decision to prescribe within their own area of practice and training (e.g. physicians for adults should not be prescribing for children) and the decision to prescribe should be agreed by the multidisciplinary team.

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<sup>3</sup> To note cannabis-based products for medicinal use relates only to cannabis and cannabis preparations (such as extracts from cannabis as well as cannabinoids isolated from cannabis). It does not include synthetic versions of naturally occurring cannabinoids (e.g. Dronabinol) or any non-natural cannabinoids obtained by chemical synthesis (nabilone).

Any decision to prescribe must take into account the relevant [GMC guidance](#) and the relevant NHS Trust governance procedures for unlicensed medicines in the normal way. As a minimum, we would expect that approval for use is granted on a named patient basis by the Drug and Therapeutics Committee Chair or Trust Medical Director. It is also good practice to discuss use of cannabis-based products for medicinal use with a peer clinician in the same Specialist Register of the General Medical Council. Any such discussions should be appropriately documented.

The regulations are drafted in such a way that cannabis-based products for medicinal use can be supplied under the prescription or direction of a specialist doctor. We are exploring how this may work under shared care arrangements, however in the first instance we expect specialist prescribing only. Trusts will meet the costs of this, where necessary. The current position is that no cannabis-based products for medicinal use are routinely commissioned by NHS England. When licensed they will become subject to normal NHS appraisal and commissioning processes.

Prescribers are expected to only prescribe a product where they are certain of its content and quality. Products would be expected to fulfil the requirements of the Medicines and Healthcare products Regulatory Agency (MHRA) specials guidance and the additional cannabis guidance: [The supply, manufacture, importation and distribution of unlicensed cannabis-based products for medicinal use in humans 'specials'](#). For example, a product should not be prescribed where the content of cannabinoid constituents (i.e. THC/CBD, as appropriate) in the product is not known or not declared on the product label.

Cannabis-based products for medicinal use may impair a person's ability to drive safely, and patients should be advised of the risks. Further information is available on the Department for Transport website [here](#), which includes information on statutory medical defence.

We expect clinicians in a non-NHS setting to follow similar standards and equivalent processes for prescribing unlicensed special medicines, bearing in mind GMC and MHRA guidance.

## **Monitoring**

Controlled Drug Accountable Officers (CDAOs) have a statutory responsibility to secure the safe management and use of controlled drugs. They must ensure (and be assured) that procedures are in place within the organisation(s) for which they are responsible to demonstrate this. This includes a duty to monitor the prescribing, supply and administration (if applicable) of all controlled drugs. You should take advice from the relevant CDAO (or local lead CDAO) and your local medication safety officer on what [additional] governance may be required to ensure the safe introduction of cannabis-based products for medicinal use in humans into clinical practice.

In the meantime the NHS England local lead CDAO will be liaising with their CDAO colleagues to ensure that the introduction of these products is monitored.

We are currently exploring options for national data collection on prescribing of cannabis-based products for medicinal use in the NHS and private sector. Further details on this will be made available in due course.

## Clinical Guidelines

To support specialist clinicians' prescribing decisions, 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 guidance is expected by October 2019 at the latest.

In the interim, NHS England asked the British Paediatric Neurology Association (BPNA) to develop clinical advice on the use of cannabis-based products for medicinal use in paediatric patients with certain forms of severe epilepsy. NHS England has also asked the Royal College of Physicians (RCP) to develop additional advice around prescribing of cannabis-based products for medicinal use in intractable chemotherapy induced nausea and vomiting and chronic pain. Both the BPNA and the RCP advice is available here: [RCP Interim Guidance](#) and [BPNA Interim Guidance](#). Information for patients and the public will be available from 1 November here: [www.nhs.uk/conditions/medical-cannabis](http://www.nhs.uk/conditions/medical-cannabis).

Alongside this we are working with the National Institute for Health Research (NIHR) to ensure their themed call "cannabis-based products for medicinal use" attracts research proposals that will address NHS priorities and emerging clinical practice.

## Pharmacovigilance

If cannabis-based products for medicinal use are prescribed then treating clinicians should maintain a detailed assessment of clinical and patient outcome measures to support patient safety and longer term understanding of the effectiveness of cannabis-based products for medicinal use. This will include reporting all suspected adverse reactions to the product (both licensed and unlicensed) to the MHRA's Yellow Card Scheme.

Yours sincerely,

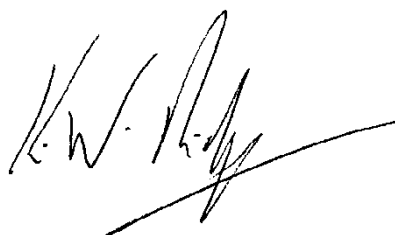


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## Annex I

### Types of Products

Cannabis has many active chemical constituents and two of these constituents, tetrahydrocannabinol (THC) and cannabidiol (CBD) have been investigated the most in respect of their medicinal value. THC is the major psychoactive constituent of cannabis and is considered responsible for giving so called “highs” to users of cannabis. CBD on the other hand, is not psychoactive.

Products falling within Schedule 2 will contain varying quantities and ratios of THC and CBD and may be available in a range of pharmaceutical forms, including as the herbal material (grown as a medicinal product and passing a quality threshold) or as extracts formulated for example as oils and capsules. Manufacturers should adhere to Good Manufacturing Practice. "Pure CBD" is not a controlled drug for the purposes of the 1971 Misuse of Drugs Act.

There is also a wide range of other cannabis products available on the internet and in some commercial outlets such as health food outlets and from cannabis ‘dispensaries’ internationally. These products are of unknown quality and contain CBD and THC in varying quantities and proportions. In the opinion of the Home Office (see its guidance note [here](#)), any CBD product that contains any amount of THC will be a controlled drug within the meaning of the 1971 Misuse of Drugs Act, except under very specific circumstances. Therefore using cannabis-based products that do not meet the official definition of a cannabis-based product for medicinal use (such as home-grown or street cannabis) for therapeutic benefit is illegal and potentially dangerous and patients should be reminded of this. The evidence that cannabis and some of its constituents can be addictive and harmful is well known and is not disputed by recent science.

The health harms of smoking are clear, therefore the regulations prohibit both the prescription and self-administration of a cannabis-based product for medicinal use in humans by way of smoking other than for research purposes, and patients should be informed of the health risks associated with such use.

### Current Licensing

Sativex® - (cannabis extracts containing THC and CBD) is the only licensed cannabis based medicinal product that is available in the UK. It has been authorised by the Medicines and Healthcare products Regulatory Agency (MHRA) as a treatment for spasticity in multiple sclerosis since 2010. Sativex is listed under Schedule 4 of the Misuse of Drugs Regulations 2001 at present. However Sativex® is currently subject to a NICE ‘do not do’ recommendation: *Do not offer Sativex to treat spasticity in people with MS because it is not a cost effective treatment.*

To date, the MHRA has licensed **no** other cannabis based medicinal products as medicines. However, two synthetic cannabinoids that are not covered in the above definition are available: nabilone, a synthetic, non-natural cannabinoid, is licenced in the UK for use in treatment resistant nausea and vomiting caused by chemotherapy; and dronabinol, a synthetic nature-identical, version of THC is listed under Schedule 2 of the Misuse of Drugs

Regulations 2001, but it does not have a Market Authorisation from the MHRA in the UK, although it is available internationally.

**Manufacture, importation, distribution and supply**

[MHRA guidance](#) sets out the requirements for the manufacture, import, distribution and supply of cannabis-based products for medicinal use. This applies the same principles that apply to other unlicensed medicines, and manufacturers and importers of these products will require the necessary licences issued by the MHRA.