Lindsey Lodge Hospice and Healthcare

Cannabis & Medicinal Use

Contents

Cannabis and Medicinal Use of Cannabis Products

The law

Cannabis has historically always being a Schedule 1 drug within the Misuse of Drugs Regulations 2001 ("the 2001 Regulations") and Misuse of Drugs (Designation) Order 2015.

On the 1st November 2018, the law changed to reschedule cannabis-based products for medicinal use in humans to Schedule 2 of the 2001 Regulations and to impose additional access and administration restrictions in relation to these products. This means that there is now a legal route for cannabis based products for medicinal use to be prescribed by doctors on the General Medical Council (GMC) specialist register in the strictly controlled circumstances without the requirement for a Home Office licence.

The 2018 Regulations introduce a definition of 'cannabis-based product for medicinal use in humans'. Only products meeting this definition will be rescheduled to Schedule 2 of the 2001 Regulations and de-designated from the 2015 Designation Order. Any other substance or product (which is or contains cannabis, cannabis resin, cannabinol or cannabinol derivatives) will remain a Schedule 1 drug. Smoking of cannabis and cannabis-based products for medicinal use in humans continues to be prohibited.

National Institute for Health and Care Excellence (NICE) have released their guidance in November 2019. This sets out the specific clinical situations medicinal cannabinoids may be prescribed by a specialist medical practitioner with a special interest in the condition being treated:

- ✓ Nabilone may be used for intractable chemotherapy-induced ***nausea and vomiting*** as add-on therapy to optimised conventional anti-emetics.
- ✓ In ***chronic pain***, cannabinoids should not be offered, unless as part of a trial. Those already established on cannabis-based medicinal product for chronic pain may continue until it is appropriate to stop
- ✓ THC: CBD spray (Sativex) may be offered as a 4 week trial to treat moderate to severe ***spasticity*** in adults with Multiple Sclerosis. This should be initiated by a physician with specialist expertise in treating spasticity.
- ✓ There are research recommendations on the use of cannabis-based medicinal products for severe treatment-resistant ***epilepsy***.

Cannabis based products for medicinal use in humans remain subject to the strict requirements of Schedule 2 to the 2001 Regulations, along with other harmful substances, such as morphine, ketamine and fentanyl.

- Safety Custody
- Prescription requirements
- Marking bottles
- Mandatory requisition forms
- Record keeping
- Destruction

Products

The cannabis plant can produce at least 144 naturally occurring compounds known as cannabinoids. The most widely researched cannabinoids are Δ9-tetrahydrocannabinol (THC) and CBD. THC is the primary constituent of cannabis that causes the "high" whereas CBD is not intoxicating at typical doses. Several different products exist for medicinal use and these differ in THC/CBD profile, formulation, licensed indications, and conditions for prescribing.

Legal preparations

Some cannabis based products were already available for medicinal use before rescheduling in 2018.

> Sativex, an oral spray derived from the cannabis plant containing THC and CBD in a 1:1 ratio, is licensed for the treatment of spasticity in multiple sclerosis.
>
> Epidiolex, an oral CBD solution derived from the cannabis plant, was licensed by the US Food and Drug Administration in June 2018 for the treatment of seizures in two rare and severe forms of childhood epilepsy—Lennox-Gastaut syndrome and Dravet syndrome. At the time of writing, an application for the same indication is under review by the European Medicines Agency, and it can currently be prescribed on a named patient basis in the UK.
>
> Dronabinol and nabilone are synthetically produced medicinal products that mimic the effects of THC. Dronabinol has an identical structure to THC, while nabilone has a related structure and is more potent than dronabinol.

Non-medicinal products

CBD products are also widely available in health food shops and on the internet in the UK and elsewhere and are not scheduled or regulated as medicines. Their THC or psychoactive content is legally controlled not to exceed 0.2% in the EU. As with other herbal remedies, the declared contents of non-medicinal CBD preparations is variable, and often inaccurate, and these products sometimes exceed the legal limit of THC. Moreover, the amount of CBD in these products is typically far lower than in clinical trials (e.g. 25 mg in a non-medicinal product versus 150-1500 mg/day in clinical trials). We should advise patients that these widely available CBD products lack quality assurance and should not be treated as medicines, but may interact with other prescribed medicines.

Why and how are cannabis based products and cannabinoids therapeutic (or harmful)?

THC and CBD have contrasting mechanisms of action on the endocannabinoid system, which is widely expressed in the central and peripheral nervous systems. These actions may account for their therapeutic effects. For example, CBD increased plasma endocannabinoid levels in a clinical trial in schizophrenia, which correlated with the degree of symptom improvement. When taken together with THC, CBD may offset some of the adverse effects of THC, such as memory impairment and paranoia. Therefore, the balance of THC and CBD may contribute to safety as well as therapeutic effects. CBD has an excellent safety profile and is well tolerated, even at high doses. THC carries an increased risk of adverse events (including serious adverse events). In a systematic review and meta-analysis, cannabinoids (primarily THC) were associated with a fivefold increase in rates of disorientation and dizziness, compared with placebo or active comparators.

What is the evidence underpinning medicinal use of cannabis-based products and cannabinoids?

There have been a limited number of randomised trials for unlicensed cannabis-based products, partly attributable to the regulatory challenges of conducting research on drugs in Schedule 1. Removing these barriers is an important benefit of rescheduling, which should lead to a stronger evidence base to guide clinical decision making. At the time of writing, the UK National Institute for Health Research (NIHR) has pledged dedicated funding and has called for grant proposals to investigate cannabis-based products for medicinal use.

Limitations of current evidence include the inappropriate handling of withdrawals from treatment, selective reporting of outcomes, and inadequate descriptions of randomisation, allocation concealment, and blinding. Heterogeneity in the types of product tested, including differences in pharmacokinetics and the balance of THC and CBD content, makes it difficult to establish optimal therapeutic formulations and dosing regimens. More larger and rigorous clinical trials are needed, including further exploration of dose-response and interactions with other medicines. For example, both nabilone (THC) and epidiolex (CBD) may increase the effects of central nervous system depressants such as alcohol. Epidiolex is metabolised by cytochrome P450 enzymes and may increase the risk of adverse effects from other medicines metabolised by this pathway, such as clobazam and valproate.

Organisation Legal Position and Policy of Practice

It is recognised that palliative care patients may have prescribed, or explore self-medication, of symptoms using cannabis and related products, particularly for the management of difficult to control symptoms. Patients whose symptoms are inadequately controlled on their legally prescribed medication, should be assessed holistically and may require input from counselling or clinical psychology.

- ✓ Medicinal preparations prescribed by a specialist (as per NICE guidelines) may continue to be used on Lindsey Lodge premises in the same way as other prescribed medication. Safe storage and handling practices as per Schedule 2 drugs will be deployed.
- ✓ Medicinal preparations (oils or capsules) purchased from a health shop, should be treated in the same way as any other herbal remedy. The medical team need to be informed in the event of any drug interactions or risk of harm. If there is risk of harm, the patient will be advised to stop the preparation. Patients should be given cautionary advice regarding the uncertain constituents of such products and the lack of evidence for cannabis products at this dosage. Patients must have mental capacity to self-medicate the product in order to continue its use on hospice premises.
- ✓ Medicinal preparations (oils or capsules) purchased on-line or via informal networks often have ratios of THC and CBD that are illegal. Due to the potential illicit status of such preparations, their use on hospice premises is not permitted.
- ✓ Non-medicinal preparations of cannabis are a Schedule 1 drug, which means it is illegal to be in possession of or use them within the UK. Lindsey Lodge Hospice & Healthcare cannot condone the use of illegal substances on organisation premises.

It is an offence for an occupier or manager of any premises to knowingly permit / allow the unlawful use or supply of illicit drugs on premises they occupy or manage

- Patients already known to use (or suspected of using) illegal substances must be warned prior to admission that illegal substances must not be brought onto Hospice premises, and that any illegal substances discovered in the Hospice will be confiscated.

If there is suspicion or knowledge of the use of an illegal substance, the following action should be taken:

- The patient will be advised that the hospice cannot condone the *use of* or *possession* of illegal substances on hospice premises.
- Upon discovery of an illegal substance, it will be removed, labelled and locked in the controlled drug cupboard.
- The senior manager of the unit will be informed and an incident record completed
- The medical team and Medical Director will be informed, in the event of any drug interaction with prescribed medicines, and for further assessment of uncontrolled symptoms.
- All illicit substances will be destroyed in line with current Controlled Drugs destruction procedures, following discussions with the police as appropriate.
- If the activity continues, the senior manager will be informed again for further action. Further action will consider the reasons for the illicit drug use and further exploration of other ways to support the individual. This action may also include exclusion from hospice premises and involvement of the police.
- Individuals who are supplying illicit substances and bringing them onto hospice premises may also be excluded and reported to the police.

REFERENCES & FURTHER READING:

1. Home Office Circular 2018: Rescheduling of cannabis-based products for medicinal use in humans
2. BMJ 2019;365:l1141

3. NICE Guideline NG144: Cannabis-based medicinal products: November 2019

Lead Author of Policy: Lucy Adcock

Responsible Sub-group Quality Assurance Committee

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