

**Recommendations** and **Guidance** on  
Medical Cannabis under Prescription

# Medical Cannabis Clinicians Society

## All-Party Parliamentary Group for Medical Cannabis under Prescription.



Medical Cannabis  
Clinicians Society

Guidance on the use of cannabis-based  
products for medicinal use | 2019

Written by  
the **MCCS** & the **APPG**

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# 1. Background

In June 2018 the Home Secretary announced a review to look into the scheduling of cannabis under the Misuse of Drugs Regulations 2001.

The first part of the review was conducted by Professor Dame Sally Davies DBE FRS FMedSci, the Chief Medical Officer for England [1]. Her review found conclusive evidence of the therapeutic benefit of cannabis-based products for certain medical conditions and reasonable evidence of therapeutic benefit in several other medical conditions. She recommended 'that the whole class of cannabis-based medicinal products (CBPMUs) be moved out of Schedule 1 of the Misuse of Drugs Regulations.'

The Advisory Council on the Misuse of Drugs (ACMD) then published their interim findings in July 2018 [2] and agreed that cannabis products should be rescheduled, subject to certain provisos.

The Home Secretary and the Secretary of State for Health and Social Care published the details of the rescheduling on 1st November 2018 [3]. Guidance was also issued for the public [4]. **The Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015** was amended to reschedule cannabis-based products for medicinal use in humans to Schedule 2 of the Misuse of Drugs Regulations 2001. That meant that from 1st November 2018 there was a legal route for cannabis-based products for medicinal use to be prescribed by doctors on the General Medical Council (GMC) Specialist Register without the requirement for a Home Office licence.

The simultaneous letter [5] from the Department of Health and Social Care and NHS England referred to additional guidance from the Royal College of Physicians [6] and the British Paediatric Neurology Association [7]. The Medical Cannabis Clinician's Society (MCCS) and the All-Party Parliamentary Group for Medical Cannabis under Prescription (APPG) feel that it is important for medical practitioners to be fully aware of the range of opinion and evidence on this matter in order to reach a balanced prescribing decision in the best interests of their patients. The MCCS and APPG hope that this guidance assists in that process.



## 2. UK Regulations

### 2.1 Who can prescribe?

A medical practitioner on the GMC Specialist Register of the General Medical Council or a **doctor under their direction** (para 7.13 of Explanatory Memorandum to the Misuse of Drugs (Amendments) (Cannabis and Licence Fees)(England, Wales and Scotland) Regulations 2018 No. 1055) can prescribe [8].

### 2.2 What can they prescribe?

**THE MISUSE OF DRUGS (AMENDMENTS) (CANNABIS AND LICENCE FEES) (ENGLAND, WALES AND SCOTLAND) REGULATIONS 2018** define a cannabis-based product for Medicinal Use (CBPMU) as follows:

“(a) is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative (not being dronabinol or its stereoisomers);  
(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;”

If the three limbs are met, then the preparations or products are considered as a ‘cannabis-based products for medicinal use in humans’ and a Schedule 2 drug under the 2001 Regulations.

It is worth noting that **Nabilone** and **Dronabinol** and any other synthetic cannabinoids are excluded from this definition, as is **Sativex (Nabiximols)** which already has a licence for use in resistant spasticity in multiple sclerosis **under Part 1 of Schedule 4 of the Misuse of Drugs Regulations 2001**.

At the time of writing, the precise products that will be available for prescription are not known. It is known that products will need to meet stringent quality controls so that the prescriber can be satisfied about safety and consistency of the product. The Medicines and Healthcare Regulatory Agency (MHRA) has produced advice on the importation of appropriate products [9,10]. The product should be properly and clearly labelled so the prescriber can readily determine the dose (such as each capsule contains 1mg THC and 20mg CBD, for example).

The MCCC and the APPG feel that, as a minimum, the proportion and dosage of CBD (cannabidiol) and THC (tetrahydrocannabinol) should be clearly labelled. Preferably the products should also list any other minor cannabinoids and terpenes and a Certificate of Analysis should be available. Advertising of unlicensed products will not be allowed.

It should be noted the CBD products (usually hemp derived) which contain no, or very little THC – less than 0.2% - are legal [11] and readily available from retail outlets (see Definitions section).

### 2.3 The mechanism for prescription

The CBPMU will be prescribed under the “Specials” system on a “named patient” basis. The prescribing doctor will need to be familiar with the regulations around a “Specials” prescription. They will be expected to prescribe within the boundaries of their knowledge and not prescribe if licenced or “off label” products are available and have not been





used. It is not mandated that **all** such products be tried first and CBPMUs are not necessarily medicines of last resort. It is up to the prescriber to determine the reasonable use of CBPMUs for an individual patient, having regard for the evidence for cannabis use in similar cases and the evidence in general for that indication and clearly having regard to the circumstances of the individual patient.

**It is up to the doctor to make that final decision and not up to any external body to do so.**

The doctor should be fully aware of the GMC Guidance on prescribing unlicensed medicines [12] and of the clinical governance procedures in their own Trust. It is good practice to seek confirmation from the Trust Medical Director or similar individual (the responsible person may vary from Trust to Trust) and seek confirmation from a peer colleague.

## 2.4 What conditions can be prescribed for?

There are **no restrictions** with regard to specific conditions. It is **not** just those conditions for which some guidance has been produced (nausea and vomiting during chemotherapy, chronic pain and childhood epilepsies).

## 2.5 Who pays for the prescription?

The prescription will be paid for by the NHS Hospital Trust if it is a valid NHS prescription. Private

prescription (with similar governance arrangements and Good Practice Guidelines) is also possible.

## 2.6 How is the CBPMU administered?

The Regulations exclude the use of smoking. Other forms of ingestion or application are thus presumably allowed (for example: vaporising, edibles, creams, tinctures, capsules, oils, sprays, suppositories, pessaries). However, it is likely that **capsules and oils for under-the-tongue use** will be the commonest form of prescription.

## 2.7 General Medical Council (GMC) advice

The GMC has made it clear that if a doctor follows the guidance and comes to a prescribing decision based on the evidence available and considers it in the best interest of that patient then no action would be taken against that doctor. Some doctors have expressed concern on this point but can be reassured. The APPG has received such reassurance from Sir Terence Stephenson, then Chair of the GMC in a letter dated 10th November 2018. The following quote is relevant:

“We have made clear that where doctors prescribing cannabis-based products for medicinal use (CDMPs) are working in partnership with patients, following the law and clinical guidance, and making prescribing decisions in good faith on the basis of evidence and experience, we would not have concerns.”

## 3. Definitions

The MCCA and APPG are aware of a level of confusion surrounding terminology.

This section should provide clarification.

### 3.1 Full extract cannabis oils (FECO)

These are oils extracted from the cannabis plant (usually the unfertilised female flower) using various extraction techniques (such as alcohol or super-critical CO2 extraction). The oils contain a mixture of cannabinoids and terpenes (and other components such as flavonoids) in proportions according to the strain of plant and the type of extraction technique.

There is some emerging evidence that FECO have better medical efficacy with less side effects than a pure isolate (see below) in accord with the recognised entourage effect. However, this hypothesis has not been tested in clinical trials.

### 3.2 Pure isolates

Some manufacturers produce pure cannabinoid isolates. Sativex, for example, is a 50:50 combination of just CBD and THC and does not contain any significant amount of other cannabinoids or terpenes. Likewise, Epidiolex (see Epilepsy section) is a pure CBD product.

### 3.3 Hemp products / CBD-only products

Hemp-based CBD products that contain less than 0.2% of THC are legal in the UK and can be purchased online or over-the-counter in health food stores. They cannot be marketed with any medical claims.

Hemp is a cannabis plant that has been bred to produce CBD but very little other cannabinoid. It is often used for non-medical products such as animal feed, rope and building material, etc. If individuals buy such products for medical use they will need to be aware that they do so without any medical guidance on efficacy or dosage as the supplier is not allowed to make medical claims. Doctors should be aware that some patients may be using CBD-only products for their medical condition. As far as the MCCA is aware, CBD products that meet necessary quality standards as documented in this report can be prescribed under the current legislation.





### 3.4 Street cannabis

Illegal cannabis products obtained on the black market are generally high in THC and low in CBD. These products are designed for the recreational “high” and such products have an increased incidence of side effects, particularly mental health problems (see side effects section). Generally, medical cannabis products are lower in THC and also combined with CBD, which counteracts the effects of THC. There is overlap between street cannabis and medical cannabis but the side effects of medical cannabis are generally much less than those of street cannabis and the two should not be confused. For clarity: the MCCS and the APPG are not advocating the legalisation of cannabis for recreational use.

### 3.5 Cannabis plant

There are two main types of cannabis plant – Cannabis Sativa and Cannabis Indica. They are said to have somewhat different recreational effects but in medical terms it is best to focus on the proportion of the different cannabinoids. The cannabinoids are mainly produced in the unfertilised female flower. The cannabinoids in the plant are in their acidic form (such as THCA (tetrahydrocannabinolic acid) and CBDA (cannabidiolic acid)). Whilst the acidic cannabinoids have some medical properties, they are usually heated to decarboxylate them in most cannabis medical capsules and oils. If dried flower is prescribed (as in Canada, for example) then it is important to remind the patient that decarboxylation by heating is required before use. Acidic cannabinoids are not psychoactive.

### 3.6 Cannabinoids

The plant contains about 120 cannabinoids. The best known are THC (tetrahydrocannabinol) and CBD (cannabidiol). The former is the main psychoactive

cannabinoid and the latter is not psychoactive and counteracts the THC psychoactivity. Most medical studies have been conducted on these two cannabinoids. The other cannabinoids studied also have medical properties. THCV, for example, (tetrahydrocannabivarin) is known to have marked anti-obesity effects. Some are psychoactive and some are not. The content label of the product should indicate the amount of the other “minor” cannabinoids but at the moment most emphasis will be on the proportions of THC and CBD.

### 3.7 Terpenes and flavonoids

Terpenes give cannabis its characteristic smell and flavonoids give colour. They also have medical properties and some patients are aware that they prefer a particular strain with a certain mixture of terpenes and minor cannabinoids. The MCCS recommend that labelling of products includes at least the terpene profile so that our understanding of the value of these components can develop over time.

### 3.8 Endocannabinoid system (ECS)

This is the neurotransmitter system contained throughout the human body. There are natural endocannabinoid receptors (CB1 and CB2) found in the nervous and immune systems and elsewhere. There are natural ligands to these receptors (anandamide and 2-AG). The ECS is known to have a wide range of effects. The phytocannabinoids found in the plant are thought to work through the ECS (and other neurotransmitter systems). There is now a wide range of information available about the science of the ECS. The MCCS recommends that doctors familiarise themselves with at least the basics of this system in order to better understand the plant / human interaction.

## 4. Evidence

It is not the purpose of this document to provide a definitive scientific review of the evidence for cannabis use in different medical conditions. The reader can refer to a number of review publications on the subject (see References) and the MCCS recommend that a prescribing physician is fully familiar with the evidence relating to their particular area of expertise. The MCCS make general comments and broad recommendations, but the prescribing decision is for the doctor who must come to their own decision. The MCCS recommend that given that there are few doctors familiar with cannabis medicine, a specialist does not refuse prescription based on their own lack of understanding but seeks to work with an expert cannabis physician. There are many examples of joint working / shared care arrangements in many branches of medicine and medical cannabis should not be an exception.

### 4.1 Cannabis evidence

Many would criticise cannabis medicine for having little hard evidence from the standard double-blind randomised placebo-controlled trials. The MCCS agree that more evidence is needed for many indications. However, the MCCS also point out that cannabis has been used for centuries by many millions of people and much is known about efficacy and side effects from this accumulated experience. Such experience should not be lightly dismissed.

The MCCS also point out that double-blind trials will be very difficult to conduct. If one takes chronic pain as an example, It is known that many people will respond to a high CBD / low THC product but that others will need a more balanced product and some will respond best to a high THC / low CBD product. The experience of Canadian producers confirms that a whole product range from high CBD to high THC is required to satisfy the requirements of those in chronic pain. Thus, any one strain, as would be needed for a single product and single indication trial, would only assist a relatively small proportion of patients and thus is likely to fail a statistical analysis against placebo. The lack of evidence from single-strain cannabis double-blind placebo-controlled trials should not necessarily be interpreted as lack of efficacy for the family of these medicines as a whole.

A broader analysis of evidence from many sources is required. This point is not widely understood by many practitioners. The generally mild side effect profile (particularly of the high CBD products) needs to be taken into account, and the side effects of alternative medications also needs to be considered. Such as opioids for pain or multiple anti-epileptic drugs (AEDs) for epilepsy, as well as the effects of continuing symptoms (such as the damage from ongoing epilepsy in childhood epilepsy syndromes).



## 4.2 Cannabis as personalised medicine

It is clear that there are many strains of cannabis with varying proportions of THC and CBD and other components. **Cannabis is not a single medicine but a whole family of medicines.** There is much trial and retrial to cannabis medicine and there is no single strain that suits any particular condition. It can take some weeks for the physician and the patient to find the right medicine and the right dose.

## 4.3 Cannabis and quality of life

The MCCC wish to point out that cannabis can help many symptoms but rarely is a cure for any condition. Thus, prescribing doctors need to bear in mind that cannabis can be used for improvement in quality of life and they need to avoid a disease-oriented approach. Take cancer as an example. There is certainly some early evidence that many cannabinoids have anti-cancer properties. There are many case studies in man showing that cannabis may reduce tumour

load. However, the MCCC accept that the overall evidence for a “cure” of some cancers is thin. Nevertheless, cannabis can help many problems associated with cancer, including anti-nausea effects during chemotherapy, reduction of pain, reduction of spasticity in nervous system tumours, reduction of anxiety, improved sleep and improved appetite. Thus a prescription of cannabis for a patient with cancer may be a very reasonable consideration for an improved quality of life.

## 4.4 Conclusive or substantial evidence of effectiveness

The MCCC now consider the evidence in specific conditions. These comments are based upon the conclusions of the National Academies of Sciences, Engineering and Medicine [13]. There is broad (but not complete) consensus on the evidence from the influential and thorough reports listed in the reference section [13,14,15,16,17,18].

### 4.4.1 Spasticity –

Most studies have been conducted with Sativex which is licenced for treatment resistant, moderate

or severe spasticity in multiple sclerosis. It is a Schedule 4 product and can be prescribed (subject to National Institute of Care Excellence (NICE) limitations). FECOs rather than pure isolate products have been studied but without such robust evidence.

### 4.4.2 Pain –

The MCCC consider that cannabis should not be first line treatment for chronic pain management as there are acceptable licenced products available. However, the MCCC has doubts about the wisdom of using opioid medication before cannabis for chronic pain. The side effects of opioids and the risk of death from overdosage are well known. The MCCC are aware of the “opioid sparing” effect of cannabis, whereby the dose of opioids can often be reduced or even stopped after the introduction of cannabis.

The MCCC consider that serious consideration should be given to using cannabis medicine when otherwise opioids may have been considered. The MCCC suggest trying a high CBD / low THC product at first before moving, if necessary, to a more balanced product and finally a high THC / low CBD product.

#### 4.4.3 Nausea and Vomiting in Chemotherapy –

The MCCC recommend that standard licenced therapy is first choice but feel that, given the side effect profile and associated benefits (such as appetite stimulation), that cannabis products should be given consideration fairly early in the treatment plan.

#### 4.4.4 Epilepsy –

The Academies report felt at the time of publication (2017) there was insufficient evidence for use in epilepsy. Since then further studies have been reported and Epidiolex (GW Pharmaceuticals) has been approved for use by the FDA in the United States for Dravet and Lennox Gastaut syndromes [19,20]. The MCCC are aware of emerging evidence [21] with regard to efficacy of full extract products with the possibility of having fewer side effects and requiring a lower dose than Epidiolex. Whilst specific studies are lacking there is no logical reason why cannabis medicine should not be used for any epilepsy in childhood or adulthood which is resistant to standard drugs. The relatively safe side effect profile and the side effects of standard medication needs to be borne in mind as well as the effects of continuing seizures. The MCCC do not recommend cannabis as first line medication but equally do not consider it should be a drug of last resort. The MCCC does not disagree with Epidiolex being used first but consider that if Epidiolex is not particularly efficacious then a full extract product should be considered which may contain a small amount of THC. The MCCC are not aware of any evidence that has found that a small

dose of THC combined with CBD is damaging to the developing brain in children. It would be a matter for the prescribing physician to use the best product for the individual.

### 4.5 Moderate evidence of effectiveness

#### 4.5.1 Sleep –

There is improvement of short-term outcomes in those with obstructive sleep apnoea syndromes, fibromyalgia, chronic pain and multiple sclerosis. These are the diagnoses in which studies have been undertaken but there is no reason why sleep disturbance in other conditions should be not be helped.

### 4.6 Limited evidence of efficacy

- **Increasing appetite** and decreasing weight loss, particularly in HIV/AIDS.
- **Anxiety** – the MCCC consider there is some evidence for the use of a CBD product for anxiety states. The MCCC recommend that such prescription is considered before every licenced anti-anxiety medication has been tried although clearly licenced product categories should be prescribed first – just not every drug in each category.
- **Post-traumatic stress disorder**
- **Symptoms of Tourette's syndrome**
- Better outcome after **traumatic brain injury** and intracranial haemorrhage



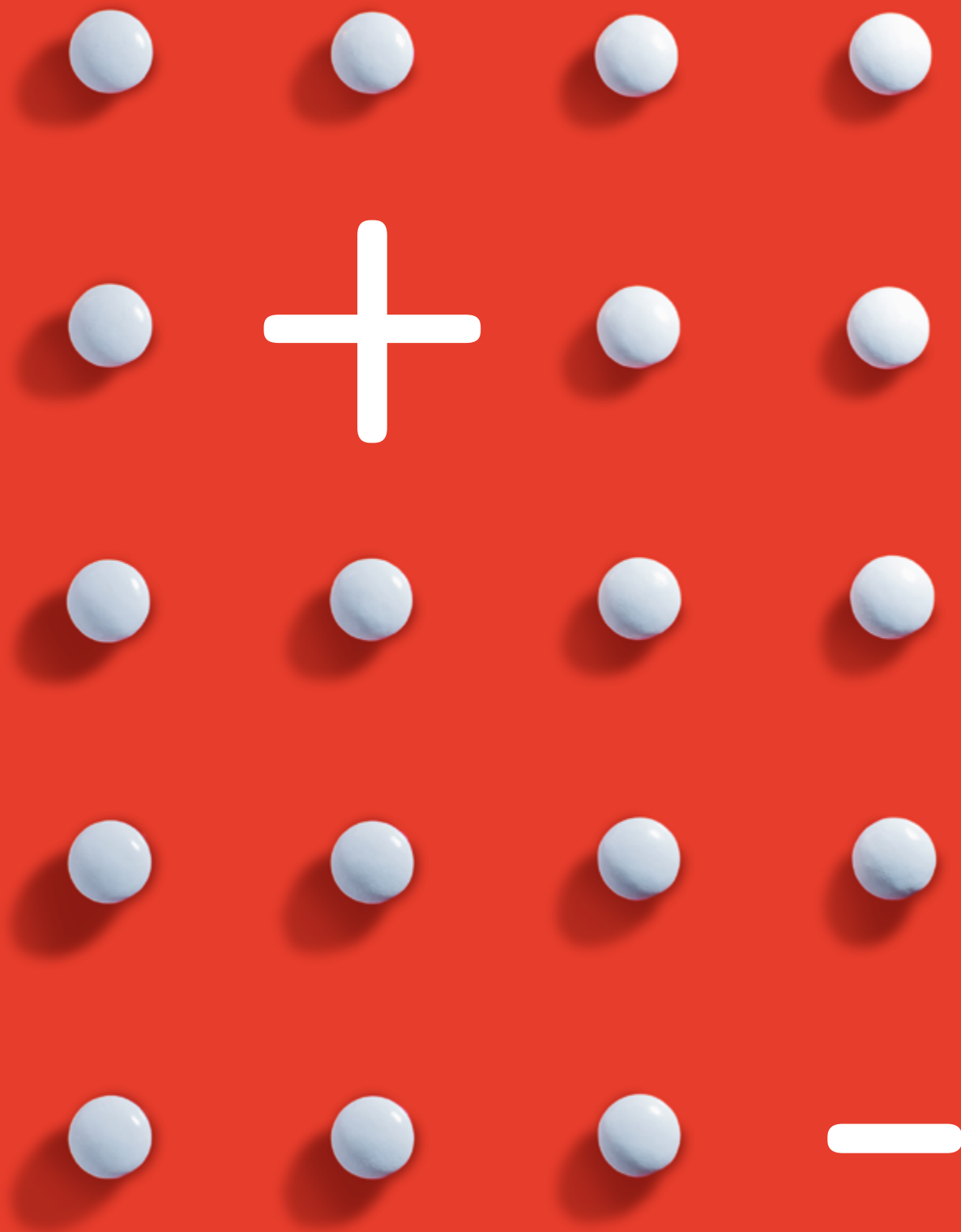
## 4.7 No conclusive evidence of efficacy

Cannabis is used in many other conditions and indeed some jurisdictions have allowed use in a large number of other disorders [22]. However, the evidence base for these conditions is lacking. This does not mean that cannabis is not effective in some circumstances but means that the studies have not allowed a firm conclusion to be drawn or have not been conducted. The MCCS note again that cannabis can be used as a product to enhance quality of life, regardless of condition, given its effectiveness for relief of pain, nausea, spasticity, sleep disturbance, poor appetite, anxiety, etc.

These conditions (not a definitive list) are:

- Motor control in Parkinson's disease
- Dystonia
- Huntington's disease
- Behavioural control in dementia
- Gastrointestinal disorders including IBS, Crohn's and ulcerative colitis
- Depression
- Obsessive compulsive disorder
- Autism spectrum disorder
- Cancer







## 5. Side effects

Prescribers need to be aware of the short-term side effects of cannabis. The MCCS note that it is mainly the THC products that produce more troublesome short-term effects such as drowsiness, dry mouth, disorientation, euphoria and confusion. These problems are more prevalent in high THC street cannabis and generally are less of an issue in lower THC medical cannabis, especially when counteracted by CBD. Patients, on higher THC products especially, should be warned **not to drive or operate heavy machinery** whilst under the influence of side effects of a cannabis product.

There is a risk of psychosis from higher THC cannabis although that risk is not entirely clear from the available literature. Nevertheless, the MCCS consider a **contraindication would be a history of schizophrenia or psychosis or a family history** of these conditions. This is especially the case in younger males.

The MCCS are not convinced of the evidence of risk of **lung cancer** from smoking cannabis but nevertheless **smoking is not an allowable mode of administration**.

There is disputed evidence of longer term **cognitive damage** from street cannabis which will tend to be high in THC. The MCCS are unaware of any evidence that there is long term damage to the developing brain from the use of relatively low THC cannabis combined with CBD, as with medicinal products used, for example, in childhood epilepsy.

Cannabis (usually high THC products) can cause high pulse rate and a relative contraindication would be a **heart condition that could be exacerbated by a high pulse**. There is limited evidence that cannabis can trigger myocardial infarction or stroke. That evidence is weak and disputed but caution is wise in people with risk factors for cardiovascular disease.

There is substantial evidence of worsened respiratory symptoms and increased chronic bronchitis episodes with long term cannabis smoking but smoking is not legally allowed or desirable.

**Cannabis use disorder** (cannabis dependency syndrome) can occur in about 9% of chronic users but these studies have largely been carried out on 'street' cannabis users with higher THC (and much less CBD) than is generally the case with medical cannabis.

**Cannabis hyperemesis syndrome** is rare complication, mainly occurring in high THC street product. It is characterised by severe vomiting that can require hospitalisation. Rehydration may be needed.

Other **contraindications** would be:

A prior **history of allergy** to cannabis or carrier oils;

**Drug interactions** need to be considered particularly clobazam prescription in epilepsy as cannabis can increase circulating levels. Other drug interactions would need to be considered by the prescriber.

Cannabis should not be used, like any other medicine, in **pregnancy** or while **breast feeding** unless absolutely essential.

There has been no reported death from **cannabis overdose**. High dose THC in overdose can cause extreme anxiety, increased pulse and paranoia and rarely psychosis, amongst other symptoms. Treatment is to wait for the effects to settle, although hospitalisation is needed occasionally for acute anxiety, panic attacks or psychosis.

This is not a definitive statement of side effects and contraindications.

## 6. Dosage recommendations

These guidelines cannot provide definitive advice on dosage for particular products but some general points may be useful.

### 6.1 Start with high CBD / low THC product

There are few medical conditions that definitely need a high THC product. Thus it is best to start with a high CBD / low THC product. The dose should slowly be increased. If the desired effect is not achieved, then changing to a more balanced THC/CBD product is the next step. Most producers make a range of products with a mix of THC and CBD in varying but broadly balanced proportions. Only if these products do not help sufficiently should a high THC / low CBD product be prescribed. In this way the side effects should be minimised. In any condition there will be some people who need a high THC / low CBD product (pain is usually a symptom which generally requires higher THC) but in most cases a high CBD / low THC or a balanced product will suffice.

In cannabis naive patients if a higher THC is to be used, after a trial of a low THC / high CBD product is not adequate, many clinicians recommend starting the THC in the evening to minimize psychoactive side effects especially in the initial 4-6 weeks of therapy and using an THC indica strain high in myrcene, which is calming and sedating so as to not adversely affect sleep.

### 6.2 Start low and go slow

A basic principle is to start at a low dose and gradually increase at, say, weekly intervals. As a rough guide most people will need around 100 to 200 mg CBD per day for the desired effect but some will need a much lower dose (see below) and a few a much higher dose.

The pure CBD products (such as Epidiolex) will need higher doses – around 10-20mg/kg is more usual. The dose of pure isolates is generally around 5 to 10 times higher than FECO products. The dose of THC is much lower. In cannabis naive patients, the THC starting dose should be 2mg at night or 1mg at night for geriatric patients or patients with a cardiac history. The dose could be escalated by about 1 to 2.5mg increments at weekly intervals until the desired effect is reached, although sometimes much slower increments are needed (see Delayed Effect below). The average efficacious THC dose is around 10 to 15mg per day but can be higher. The average required dose varies considerably from person to person.

### 6.3 Sensitive individuals

A few people (maybe around 10%) seem to need much smaller doses. These people may have issues with metabolism of cannabinoids, possibly a variant of the CYP2c9 enzyme and other enzymes. Hence an initial low dose is the best course of action.

### 6.4 Biphasic response

Sometimes cannabinoids act biphasically. An effect at a particular dose is not necessarily improved by a dose increase and indeed the opposite may be true. A higher dose may worsen the response whereas a lower dose may improve the response.

### 6.5 Delayed effect

Sometimes the positive effect of cannabinoids may be delayed. Some children, for example, can take up to 6 weeks or so to respond to a specific dose and thus caution needs to be exercised about escalating the dose too quickly.





## 7. Research

The MCCS and APPG encourage research on the medicinal effects of cannabis. There is much to be learnt about the effects of different strains on different conditions, different modes of administration and dosages. The MCCS and APPG support the themed call [23] by the National Institute for Health Research (NIHR) on “cannabis-based products for medicinal use”.

## 8. Education

The MCCS and APPG consider that a top priority is education for medical practitioners. Doctors have not been trained in cannabis medicine and many are, quite rightly, reluctant to prescribe due to their lack of knowledge. The MCCS and APPG encourage the establishment of training programmes and hope that Health Education England (and the counterparts in Scotland, Wales and Northern Ireland) will work with others to establish educational programmes in this field.







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