CBD: RECOMMENDATIONS FOR GOOD PRACTICE
UNDERSTANDING OVER-THE-COUNTER CANNABIDIOL

THE MEDICAL CANNABIS CLINICIANS SOCIETY

MAY 2022

Kindly supported by
satipharm
MCS
Medical Cannabis Clinicians Society
# Table of Contents

1. **Introduction**
2. **About the Recommendations**
3. **What Doctors and Consumers Should Expect from CBD Products**
4. **CBD Content & Type**
5. **Types of Product**
6. **Dosing**
7. **Safety**
8. **Labelling**
9. **Controlled Drugs Legislation**
10. **Medical Claims**
11. **Checklist for CBD Products**
Over-the-counter (OTC) cannabidiol (CBD) is now very popular and a multimillion-pound UK market. Many people use CBD for medical purposes despite the producers' inability to make medical claims.

It is now common for doctors and pharmacists to be asked about CBD products. As a result, these are often favoured as the first port of call for medicinal cannabis.

*Which to choose, which to advise?*

Purchasing an OTC product is more straightforward, accessible, and cheaper than a medical consultation and prescription cannabis medicine. However, there are many products on the market (258 producers have been reviewed for this guide) and a bewildering array of options.

In 2020, the Medical Cannabis Clinicians Society produced a *Clinicians’ Guide to CBD* that outlines CBD usage's basic principles but avoids specific product discussion. This *Recommendation for Good Practice* is a companion volume to the *Clinicians’ Guide to CBD*.

Thanks to Andrew Barnes ([www.tincturetailor.com](http://www.tincturetailor.com)) for work on the screening process of UK CBD companies which was the basis for this guide. In this document, "we" refers to The Medical Cannabis Clinicians Society.
CBD is available in several different formats. Currently, the most common formulation is CBD in oil, as this is the simplest format to produce - being the extract of the plant diluted in a carrier oil.

CBD is often now encapsulated as a simple oil in capsule format or more advanced capsule formulations. Capsules are becoming more popular as these avoid some of the disadvantages of oils, such as unpleasant taste, difficulty and inconsistency of dosing, and poor compliance. Additional formats, such as balms, patches and topical CBD products, are also now becoming available, which may well have medical value. However, there is little clinical evidence available on these yet.

This paper only discusses CBD in oil and capsule formats for either buccal/sublingual or oral use. For a more detailed introduction to CBD, please refer to the Clinicians’ Guide to CBD.

The Medical Cannabis Clinicians Society has considered the criteria that a medical practitioner would want to see in a good quality product.

The issue for CBD products is that there have been instances where products breach the applicable regulatory standards, either in label claims, quality, or the Misuse of Drugs Regulations. As such, we set out relevant criteria we see as necessary for products to make the grade.

A few companies have already met our criteria. These companies have been contacted and may choose to advertise that fact. That does not mean that all other products are bad, by any means. It may just mean that they need to consider a few minor adjustments to labelling, certification, etc. in order to reach our standard.

We encourage companies to make these amends.

This paper is aspirational. Our recommendations carry no force of law and simply represent our opinion.

However, we hope that these recommendations will act as an aim and a guide for the over-the-counter CBD industry. If all CBD products complied with our suggestions, we would have a safe, robust sector with good quality products and guidance.
WHAT DOCTORS AND CONSUMERS SHOULD EXPECT FROM A CBD PRODUCT

We feel that the following criteria are the basis of a good product:

1. CBD content and type: an indication of how much and what type of CBD the product contains
2. Dosing information
3. Safety information: compliance with the standards for contaminants, etc
4. Labelling: compliance with applicable food labelling standards, warnings, etc
5. Controlled Drugs legislation: compliance with the Misuse of Drugs Regulations 2001
6. Medical claims are not made
CBD CONTENT & TYPE

CBD products require clear labelling, so consumers know how much CBD they are taking. Products should provide the amount of CBD they state on the label.

In addition, Certificates of Analysis (C of A) should confirm that the stated CBD content is accurate. The regulations for prescription products require that the active ingredient(s) is within +/-10% of the label claim for the full shelf life of the product. For food supplements, the regulations permit a range of +/-20%.

For capsules, CBD content should be in mg (given the fixed nature of the dose per capsule).

For CBD oils, a label that states CBD concentration in mg/ml rather than as a percentage is preferable to simplify the dose calculation. A measured dosing pipette is also preferable to allow consumers to take a consistent dose.

The content should be confirmed by a Certificate of Analysis (C of A).

CERTIFICATE OF ANALYSIS

A readily accessible Certificate of Analysis (C of A) is essential. The C of A should tell the consumer what is in the product. It should state which cannabinoids are present, not just CBD but the amount of other "minor" cannabinoids, including the amount of controlled cannabinoids, such as THC. The terpene profile is also important for the overall effect of the product.

The C of A should clearly state that no heavy metals, pesticides and fungi are present, nor residual solvents (see safety section). It should reference a batch number of the product so any contamination issues can be properly traced. The product must clearly also have a batch number that references the C of A.

We also feel that the Limit of Quantification (LOQ) should be stated. The LOQ determines the minimum amount of a cannabinoid or terpene that can be detected by the equipment used.

Sometimes a high LOQ will miss an illegal level of a controlled substance. If, for example, the LOQ is 0.03% THC, then a product of 0.02% THC will be missed. In a 10 ml bottle, that product will be illegal and contain 2mgs THC - above the 1mg limit.

As a publicly available C of A is not mandatory, we feel we cannot insist on a Certificate that contains this level of detail. But, we wish to recognise those who have C of As, and we encourage those whose Certificate does not carry all the above detail to considering adjusting their information accordingly.

We also think it is important that the consumer knows whether an oil is full-spectrum (unlikely to be legal), broad-spectrum or an isolate. Unfortunately, these definitions are not uniformly accepted so we define these as follows, with more information overleaf:

- Full-spectrum
- Broad-spectrum
- Isolate or synthetic CBD.
TYPES OF PRODUCT

FULL-SPECTRUM

Full-spectrum CBD oil uses a refined CBD extract. The key compounds of cannabinoids and terpenes will be present along with some flavonoids. The fats, lipids, waxes and chlorophyll have usually been removed resulting in a very high-quality CBD oil.

Full-Spectrum CBD oil fully benefits from the entourage effect. By definition, full-spectrum CBD oil will contain controlled cannabinoids such as THC, CBN, or THCV. If the combined total amount of controlled cannabinoids is over 1mg per container, then the product is classed as a Schedule 1 drug under the Misuse of Drugs Regulations 2001 and is not legal to sell over-the-counter.

BROAD-SPECTRUM

Broad-spectrum CBD oil uses a further refined CBD extract. The key compounds of cannabinoids and terpenes will be present with trace amounts of flavonoids. The fats, lipids, waxes and chlorophyll have usually been removed.

Controlled cannabinoids such as THC, CBN and THCV have also been removed or largely removed. If the residual amount of controlled cannabinoids is less than 1mg per container then the broad-spectrum product will be legal to sell OTC as a food supplement.

Broad-spectrum CBD oil benefits from the entourage effect, although not as much as full-spectrum due to the loss of direct receptor binding cannabinoids such as THC, CBN or THCV.

ISOLATE OR SYNTHETIC CBD

Some products use isolate or synthetic CBD. Isolate CBD is made from whole-plant, but all cannabinoids and terpenes have been removed and only pure CBD remains. A synthetic isolate is made from other natural sources such as yeasts or citrus fruits. Again, there is only CBD present, and the product is usually 99%+ pure CBD. There are no additional cannabinoids, terpenes or flavonoids, unless added back in post-production.

These oils do not benefit from the entourage effect, and the effectiveness can be biphasic; once hitting optimal dosage, effects begin to reverse or diminish even when dosages are increased.

Isolate, or synthetic CBD does not contain controlled cannabinoids like THC, CBN or THCV. Therefore, they are not classed as schedule 1 drugs and may be sold as a food supplement.

The advantage that CBD isolate has is that WADA approves it for professional athletes. WADA does not approve the use of any other cannabinoids in competition, whether controlled or not. Isolate CBD or synthetic CBD are usually consistent and more "pharmaceutical" than plant-based products.

We encourage producers to state whether the product is suitable for athletes or those subject to drug testing. If the product contains any cannabinoid except CBD, it is not suitable. Thus a suitable product for an athlete is likely to be a pure CBD isolate. However, some products may be reconstituted, containing, for example, pure CBD and perhaps some terpenes or other food supplements added back-in during the manufacturing process. It is up to the athlete to determine whether any non-CBD added food supplements are legal under WADA rules.
Dosing is a difficult issue. The Food Standards Agency (FSA) have issued guidance that there should be a maximum of 70mgs CBD taken daily. Cannabidiol (CBD) | Food Standards Agency.

We are not aware of any scientific basis for this recommendation. Indeed, as the average dose of CBD for medical purposes is around 60-100mgs daily, then adhering to 70mgs daily will mean that many consumers will miss out on potential benefits.

We have carefully considered this issue and feel that dosage instructions should state the product should be started at a low dose (about 10mgs daily) and slowly escalated. The average required is about 60-100 mgs for good effect. Once that dose is reached, a doctor should be consulted before further escalation. We feel that this approach is reasonable.

Alternatively, or in addition, the product should state that the FSA maximum dose guidance is 70mgs. We know that the FSA does not favour a dosing escalation regime, but as this is the best way to take the product, we encourage the FSA to review its dosing guidance.

Doctors/ and pharmacists need to note and advise patients that CBD isolate and synthetic CBD products generally require higher dosing than broad and full-spectrum products. For example, Epidyolex requires much higher dosing than full spectrum oil for children with epilepsy and has more side effects. This is an example of the entourage effect.
Products must comply with the regulations around safety. These include applicable limits for heavy metals, toxins, solvents, microbes, pesticides, etc.

Again, the onus is on the producer to ensure the products placed on the market comply with these regulations.

If providing a C of A, this should clearly state the product complies with the applicable limits.

The consumer must be appropriately warned about other safety considerations.

This should include a note that children should not use the product, it is not to be used in pregnancy or whilst breastfeeding and if the consumer is on any other medication, they should consult their doctor.

This information ideally should be clear at the point of sale.

Whilst this is not compulsory from a statutory standpoint, we feel this is important information that should be given.

We also feel that a doctor/pharmacist should warn the patient about these issues. We encourage producers to make this information clear.
LABELLING

CBD CONTENT
As mentioned in section 1, the CBD content of a food supplement must be within +/-20% of the labelled CBD content for the full shelf life of the product.

We ask for clear and accurate labelling regarding the cannabinoid content.

WARNINGS & OTHER INFORMATION
Labels must disclose allergens. One such allergen requiring disclosure, for example, is sesame oil. If a CBD product uses Sesame oil as a carrier, this must be disclosed.

We advise producers to disclose the carrier oil in all cases. We also feel that products should state whether they are suitable for vegans, gluten-free, and whether suitable for kosher and halal diets.

Food supplements must also carry further information on the label:

Food supplements have their own labelling requirements, laid out in the Food Supplements (England) Regulations 2003 and equivalent regulations in Scotland, Wales and Northern Ireland.

These stipulate that:
No person shall sell a food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless the name under which it is sold is “food supplement”.
Without prejudice to the Food Labelling Regulations 1996, no person shall sell a food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless it is marked or labelled with the following particulars:
• the name of the category of any vitamin or mineral or other substance with a nutritional or physiological effect which characterises the product or an indication of the nature of that vitamin or mineral or other substance;
• the portion of the product recommended for daily consumption;
• a warning not to exceed the stated recommended daily dose;
• a statement to the effect that food supplements should not be used as a substitute for a varied diet;
• a statement to the effect that the product should be stored out of the reach of young children;
• the amount of any vitamin or mineral or other substance with a nutritional or physiological effect which is present in the product

Food Supplements: publishing.service.gov.uk

Food supplements are subject to other legislative requirements, including the Food Information Regulations 2014 and the Food Safety Act 1990. Conformity to the relevant food regulation is the responsibility of the producer/supplier and is subject to checking by local Trading Standards Officers.

Note that we have not checked the products for compliance with the Food Labelling Regulations or other food supplement regulations. Every product must ensure that what is on the label is what is in the bottle.
The Society cannot recommend products that do not follow the current Misuse of Drugs Regulations 2001 (MDR 2001).

We strongly feel that "1mg per container" rule is non-sensical but, nevertheless, is the present rule. It is not the Society's job to ignore the Regulations as they currently stand. Therefore, an OTC CBD product needs to be an "exempt" product under the Misuse of Drugs Regulations 2001.

This definition is: "An "exempt product" means a preparation or other product consisting of one or more component parts, any of which contains a controlled drug, where:

- the preparation or other product is not designed for administration of the controlled Drug to a human being or animal;
- the controlled Drug in any component part is packaged in such a form, or in combination with other active or inert substances in such a manner, that it cannot be recovered by readily applicable means or in a yield which constitutes a risk to health and;
- no one component part of the product or preparation contains more than one milligram of the controlled drug"

In practical terms, that means that any OTC product must contain less than 1mg in total per container of all controlled cannabinoids and not just THC.

Please see THC in detail explored overleaf.
There are 12 controlled cannabinoids:
- Trans-delta-9-tetrahydrocannabinol-C5
- Cis-delta-9-tetrahydrocannabinol-C5
- Delta-9-tetrahydrocannabinol-C4
- Delta-9-tetrahydrocannabinol-C3 (Delta-9-tetrahydrocannabivarin)
- Delta-9-tetrahydrocannabinol-C1
- Delta-8-tetrahydrocannabinol
- Cannabinol-C1
- Cannabinol-C2
- Cannabinol-C3
- Cannabinol-C4
- Cannabinol-C5
- Cannabinol methyl ether-C5

Simply, this amounts to THC (Delta 9 tetrahydrocannabinol C5) and the oxidised breakdown product of THC called CBN (cannabinol), as well as the lesser known THCV (delta 9 tetrahydrocannabivarin). The total amount of controlled cannabinoids and not just THC must be less than 1mg per container.

This regulation is non-sensical, as the amount in a container will clearly depend on the size of the container. So, a 10ml container with less than 1mg controlled cannabinoids will be legal, whereas the same oil in a larger container may not be.

We have looked at containers up to 30mls. Some producers offer larger size containers – 50ml or 100mls for example. In some cases, their 10/20/30 mls bottles are compliant, but because of the "1mg per container" rule, the larger bottles may not be, despite being the same oil. This regulation needs to change.

We note the recent guidance produced by the Advisory Council on the Misuse of Drugs (ACMD). We welcome the suggestion that the "1mg per container" rule be replaced. The ACMD has suggested a limit of 50 micrograms of delta 9 THC in a unit of consumption (where a unit of consumption or 'single serving' is the "typical quantity of a CBD product consumed on one occasion").

However, we feel that a "single serving" is open to wide interpretation. The ACMD has said that THC in a dose of 1mg is unlikely to produce any psychoactive effects (para 5.10 of their report). They then reduce that level by two "uncertainty" factors, first 10 times and then another 2 times to reach a suggested level of 50 micrograms per serving (para 5.14). The uncertainty factor (UF) reductions seen arbitrary and mismatched with other compounds like caffeine (UF 0), alcohol (UF 0), nicotine (UF 4.4) and codeine / morphine (UF 5). The suggested THC level seems very cautious.

We do welcome the suggestion that the 50 microgram level applies to just delta 9 THC and not all controlled cannabinoids combined, as at present.

We note that the ACMD have stated that non-delta 9 THC cannabinoids are of such low potency that they can be considered not to exert any psychoactive effect when present in consumer CBD products. Thus the ACMD have suggested that the level of non-delta 9 controlled cannabinoids is set at the same level (50 micrograms) as delta 9 (plus THCA) but separate to delta 9 and the limit would no longer be the total amount of all controlled cannabinoids.

We welcome this suggestion and have taken this into account in our company analysis. However, these recommendations have yet to be accepted by Government and we await a final decision.
MEDICAL CLAIMS

Another difficult area. An over-the-counter CBD producer is legally prohibited from making any medicinal claims about their specific product/s, which makes it difficult for the consumer to know what type of product to buy and what dose to take.

Medicinal products are regulated by the Human Medicines Regulations 2012 (HMR 2012). The UK regulator, the Medicines & Health products Regulatory Agency (MHRA) has determined that CBD is itself a medicine.

However, as long as medicinal claims are not made about it on any product packaging or linked marketing, then they will not intervene. Some of the references that may amount to medicinal claims are:

- References to medical conditions
- Comparisons to licensed medicines
- References to interference with the normal operation of a physiological function
- Product names that refer to adverse medical conditions
- Recommendations by doctors/health professionals
- Testimonials that include/imply medical claims
- Graphics that imply medicinal uses
- References to clinical research or testing
- Reference to health risk of not taking a product
- General claims that a product can "cure", "restore", "prevent", "avoid", "fight" or "heal" for example, are likely to be considered medicinal.

Making such claims without authorisation is prohibited under Regulation 279 of the HMR 2012.

Continued...
However, the fact is that CBD is a medicine with well-known and documented medical properties. It is a grey area as to what constitutes a medical claim.

Is anxiety always medical or is milder anxiety or "stress" just a wellness issue? Are all aches and pains medical or are some just everyday wellness issues?

This area is also widely interpreted by producers.

Of course, producers should not make unsubstantiated medical claims, such as curing cancer, but we consider that reasonable, balanced and accurate statements are acceptable as long as they are not product-specific.

We would not support a producer claiming that their product is better than another product/s unless they can produce scientifically valid evidence that that is the case. That is unlikely as the CBD molecule is the same from product to product.

In our opinion, it is reasonable for a product or website to carry accurate information on the known benefits of CBD.

However, perhaps a statement such as the below should be used to clarify the status of CBD as a food supplement and not an approved medicine:

"All our products are sold as food supplements only to help promote everyday well-being. They are not intended to diagnose, treat, cure or prevent any disease."

As these recommendations are a guide primarily for doctors, we hope that our colleagues in the medical and pharmacy professions will advise patients accordingly about the scientifically robust medical evidence around the use of CBD products.
As part of the UK’s leading group of medical cannabis experts, members have access to information to inform treatment decisions, up-to-date product guidance and support to ensure clinicians can become as confident in prescribing medical cannabis as they are with first line treatments.

With the most respected medical cannabis clinicians in the country providing support, members are better able to help their patients.

Annual membership is £90 for consultants, GPs and others and £45 for nurses and AHPs. Membership is free for medical students and we welcome international members.

Join online at www.ukmccs.org.

THE MEDICAL CANNABIS CLINICIANS SOCIETY

INDEPENDENT, EXPERT SUPPORT FOR CLINICIANS

The Medical Cannabis Clinicians Society is an independent community of medical cannabis pioneers – the first prescribers of this treatment in the UK.

We believe that every patient who could benefit from medical cannabis should have access to it.

We provide the medical and scientific community interested in supporting patients with medical cannabis with high-quality training and expert support.

Membership is open to those with a professional interest in medical cannabis, including clinicians, nurses, GPs, allied health professionals (AHPs), medical students, healthcare scientists, pharmacists and those working across acute, primary and community healthcare.

OUR WORK IS MADE POSSIBLE BY UNRESTRICTED EDUCATIONAL GRANT FUNDING FROM SUPPORTERS.

Meet our supporters and learn how you can help.

Meet our supporters and learn how you can help.
ESSENTIAL CRITERIA FOR CBD PRODUCTS

- Does the product have a valid Certificate of Analysis (C of A)?
- Does the product provide the amount of CBD it contains on the label?
  - For capsules, CBD content should be in mg (given the fixed nature of the dose per capsule)
  - For CBD oils, does the label state the CBD concentration in mg/ml?
- Does this amount correspond with the C of A number?
- Is the product full or broad spectrum, or an isolate?
- If it is an isolate with no traces of THC, does the label state whether the product is suitable for athletes or those subject to drug testing?
- Do the dosage instructions state the product should be started at a low dose and slowly escalated?
- Does the product state that the FSA maximum dose guidance is 70mgs per day?
- Does the C of A state that the product complies with the regulations around safety, e.g. applicable limits for heavy metals, toxins, solvents, microbes, pesticides?
- Does the product warn about other safety considerations?
  - not to be used in pregnancy or whilst breastfeeding
  - if the consumer is on any other medication, they should consult their doctor
- Does the product disclose allergens?
- Does the C of A demonstrate that it contains less than 1mg in total per container of THC and all controlled cannabinoids?
- Does the product make any medical claims?
- Is the product clearly indicated as a food supplement?