Cannabis oil and cannabidiol-containing products: pharmacy sales

Community pharmacy teams have seen a significant increase in requests for cannabis oil and cannabidiol (CBD)-containing products from members of the public in recent months. Many members have sought information on various CBD products and guidance on whether to stock/sell/supply such products from their pharmacy premises.

This guidance is intended to assist you and your team in dealing with requests for cannabis oil/CBD-containing products and provide appropriate advice to your customers.

The guidance includes:

- Information on current legislation
- Guidance on the marketing and classification of such products
- What clinical and patient-specific implications to consider
- Current statements from the MHRA, the Home Office, the Food Standards Agency (FSA) and the NPA Legal Indemnity team

As further information/guidance becomes available, this resource will be updated as required.

Cannabis

'Cannabis' is referred to by a number of different names. The various terms used to describe cannabis are explained in Table 1 below.

Table 1: Examples of cannabis terminology

Terminology	Definition and notes	
Cannabis	• Defined in UK law as any part of the plant within the genus Cannabis, containing over 60 constituents known as cannabinoids • Also referred to as marijuana, hash, weed, or bud	
Cannabinoids	**Cannabidiol (CBD) is:** • Non-psychoactive component of *Cannabis sativa* • Currently undergoing investigation for potential therapeutic uses, including control of seizures, anti-tumour effects and antidepressant effects **Tetrahydrocannabinol (THC) is:** • The psychoactive component and main active constituent of *Cannabis sativa* • Also referred to as dronabinol	**Other cannabinoids** • Include cannabinol (CBN), cannabichromene and cannabigerol **Nabilone** • Synthetic cannabinoid used as an antiemetic in chemotherapy **Sativex® is:** • A combination of CBD and THC • The only cannabinoid licensed as a medicinal product – it is a Schedule 4 (Part 1) Controlled Drug (CD) prescription-only medicine (POM)
Hemp	• Cultivated from the fibre and seeds of Cannabis sativa • Contains less than one per cent THC	

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Medicines and Healthcare products Regulatory Agency (MHRA)
Cannabis has no proven medicinal purpose, and the MHRA has stated that herbal cannabis in its raw form (also known as medicinal cannabis) does not have a licensed use in the UK**.**

In October 2016, the MHRA released a statement stating that all cannabis oil and CBD-containing products used/advertised for medical purposes in the UK will require a marketing authorisation (product licence) before they can legally be sold/supplied.

The UK manufacturers of cannabis oil and CBD-containing products marketed for medicinal purposes were given a deadline of end of December 2016 to withdraw any products from the market that did not meet legislation, or work with MHRA to satisfy the legal requirements for medicinal products under The Human Medicines Regulations (HMR) 2012. The MHRA is currently working with manufacturers and trade bodies to review cannabis oil and CBD-containing products which are not licensed as medicinal products, including their marketing and sale; currently, there is no guidance.

Cannabis oil and CBD-containing products which are **not** licensed as medicinal products by the MHRA are not required to meet good manufacturing practice, including safety, quality and efficacy standards; as a result, the safety and quality of such products may not be guaranteed. Additionally, cannabis oil and CBD-containing products which are marketed as food supplements, rather than licensed medicines, do not fall under the HMR 2012 definition of a medicinal product.

Home Office
The Home Office (HO) lists cannabis, cannabis oil, cannabis resin, cannabinol (CBN) and CBN derivatives as Class B/Schedule 1 CDs. An exception is THC (dronabinol or its stereoisomers) which is a Class B/Schedule 2 CD. The whole cannabis plant is subject to the Misuse of Drugs Act 1971; however, certain parts of the cannabis plant when separated from the rest of the plant are not subject to such regulations.

CBD-containing products, although commonly advertised to be free from THC, have the potential to contain traces of THC, even after the manufacturing process. For products containing CBD to be exempt from the Misuse of Drugs Regulations 2001, the amount of THC in each preparation **must not exceed 1mg**; this is considered by the HO to be the pack in which the preparation is contained – for example, the entire original bottle/pack (not each individual tablet or dose).

! Please note: There are many references to the legal limit of THC in a product as 0.2 per cent or less. It is important to be aware that this limit is applicable to the cultivation of cannabis plants, for the production of hemp fibre or obtaining seeds, to be pressed for oil. This legal THC limit is **not** applicable to cannabis and CBD-containing products themselves.

A common question addressed by the HO is: "*I want to grow cannabis (industrial hemp): do I need a licence*?". In response, the HO has advised that a HO license is required to legally grow and cultivate cannabis. Applicants may apply for a licence via the HO Drugs Licensing website. They do not accept applications by post or e-mail.

Food Standards Agency (FSA)
The General Food Law Regulation (EC) 178/2002 defines 'food' as *"any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans"* that does **not** fall under another product category, such as medicines, narcotics, psychotropic substances, or cosmetics. Food supplements are **not** medicinal products and therefore are not governed by HMR 2012; they are instead governed by other legislation and food laws, including the Food Safety Act 1990, The Food Supplements (England) Regulations 2003 (and Wales, Scotland and Northern Ireland equivalents)

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and General Food Regulations 2004. The FSA advise that if there are any concerns around the sale of food supplements, such as whether it is illegal or unsafe, they should be reported to the local enforcement authorities.

Patient considerations

The cannabinoid, THC, can be abused for its physiological and psychoactive effects. Although many cannabis oil and CBD-containing products claim to be free from THC, traces may still be present in these products.

Low doses of THC can cause psychological effects, such as euphoria, drowsiness, and altered perception of time. Therefore, an individual's ability to drive may be impacted; however, the specific correlation between cannabis blood levels and impairment of driving performance has not yet been established.

Regardless of this, the UK government has included cannabis (THC) under drug driving law, due to its association with illegal use. Cannabis (THC) has a specified blood limit of 2mcg/L – elevated blood levels could lead to prosecution. Further information can be found in the NPA drug driving suite of resources.

All pharmacists selling cannabis oil and CBD-containing products should ascertain the THC content and inform the customer accordingly, even if THC is present in trace amounts, as this may affect the individual's clinical/psychological status and driving ability. Cannabis and CBD may have interactions with other medication and medical conditions; therefore, clinical checks should be conducted before selling/supplying such products.

NPA Legal Indemnity statement

The NPA Legal Indemnity (NPAI) team has issued the following statement regarding NPA members selling/supplying cannabis oil and CBD-containing products, including those licensed as a medicinal product or classed as food supplements:

"Members who are considering selling or supplying cannabis, cannabis oil products, or any CBD products or derivatives must ensure that they ascertain before doing so the status of such products, and whether they require a product licence (marketing authorisation), or otherwise.

Failure to do so (and to be able to satisfy this requirement to NPA Insurance) will mean that in the event that a third party claim is made against the member's professional indemnity policy, or a request is made by the member for legal defence or representation to respond to a Regulatory or Criminal investigation, that indemnity, legal defence or expenses cover may not be provided.

If in any doubt, members are urged to contact the NPA Pharmacy team for advice in relation to selling or supplying of any cannabis product, or the NPAI team in respect of matters of policy cover."

Summary and practical considerations

There are a number of legal, professional and ethical considerations around the sale/supply of cannabis oil and CBD-containing products from community pharmacies. The legality, safety and efficacy of cannabis oil and CBD-containing products is uncertain. Guidance from the Medicines and Healthcare product Regulatory Agency (MHRA) it not yet available on the status of cannabis oil and CBD-containing products in the UK, and their suitability for sale/supply to the public.

Before deciding to stock/sell/supply cannabis oil and CBD-containing products, it is strongly recommended that you consider the following points:

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- There is limited evidence of the clinical benefits and uses of cannabis oil and CBD
- There may be potential clinical interactions with other medication that the customer may be taking (either prescribed or bought over the counter)
- What is the legal status and licensing of cannabis oil/CBD-containing products? All products which are marketed for medical purposes in the UK require a marketing authorisation (product licence) from the MHRA before they can be legally be sold/supplied
- Are the relevant products marketed as a food supplement? If so, manufacturers of food supplements are **not** permitted to make medicinal claims on the packaging or promotional material (including social media). It is inappropriate for pharmacy teams to advise customers on using cannabis oil and CBD-containing products to treat any medical conditions
- Food supplements are not required to go through rigorous safety and quality testing
- Does the product contain tetrahydrocannabinol (THC)? If so, the amount of THC in the product must **not exceed 1mg per pack/preparation**.
- THC can cause physiological and psychoactive effects, and may affect driving ability; refer to the NPA drug driving suite of resources
- Pharmacies may remain liable for any future implications until the MHRA sets guidelines

References

- MHRA: MHRA statement on products containing cannabidiol (CBD) – https://www.gov.uk/government/news/mhra-statement-on-products-containing-cannabidiol-cbd
- Home Office: https://www.gov.uk/guidance/controlled-drugs-licences-fees-and-returns
- Home Office: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/642482/Hemp-Grower_notes-2017.pdf

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