

CANNABIS-BASED products for medicinal use

The Pan Mersey Area Prescribing Committee does not currently recommend the prescribing of CANNABIS-BASED products for medicinal use.

GREY

This recommendation will be reviewed within 6 months of the licensed product launch in the UK market and / or publication of the NICE Guidelines due in October 2019.

Definition^{1,2}

The following definition of a 'cannabis-based product for medicinal use' has been formally agreed by the UK Government:

- It contains cannabis, cannabis resin, cannabinol or a cannabinol derivative.
- It is produced for medicinal use in humans.
- > It is:
 - a medicinal product; or
 - a substance or preparation for use as an ingredient of a medicinal product; or
 - a substance for use in the preparation or manufacture of an ingredient of a medicinal product.
- > This definition 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).

Reclassification¹

Cannabis-based products for medicinal use (excluding synthetic cannabinoids) have been reclassified from Schedule 1 to Schedule 2 of the Misuse of Drugs Regulations following an examination of evidence of their medicinal benefit.

Unlicensed medicines^{1,3}

- > Until a licensed product becomes available, all cannabis-based products for medicinal use (apart from Sativex®) are classified as unlicensed medicines.
- > The prescribing of unlicensed cannabis-based medicinal products must be on a 'named patient' basis in order to meet the special clinical needs of the patient (which cannot be met by a licensed medicine).
- The MHRA has produced a guideline on unlicensed cannabis products: The supply, manufacture, importation and distribution of unlicensed cannabis-based products for medicinal use in humans 'specials'.

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

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Version: 1.1

Prescribing¹

- > The decision to prescribe unlicensed cannabis-based products for medicinal use is restricted to only those clinicians listed on the <u>Specialist Register</u> of the General Medical Council (GMC). The GMC register can be searched here.
- > A Specialist clinician 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.

Sativex®1

- > Sativex® is a licensed cannabis-based medicinal product which contains both tetrahydrocannabinol (THC) and cannabidiol (CBD).
- > It is already available in the UK and is currently listed in Schedule 4 of the Misuse of Drugs Regulations.
- > Sativex® has a marketing authorisation for spasticity in multiple sclerosis. However, it is not currently recommended for use by NICE and has 'black drug' status on the Pan Mersey APC formulary.

Artisanal CBD oils and other preparations^{1,4}

- > There is a wide range of other cannabis products available on the internet and in commercial outlets such as health food stores.
- > As these products are not produced to a pharmaceutical standard, they may contain CBD and THC in varying quantities and proportions and are not tested in clinical trials for safety or effectiveness. They may possibly contain other cannabinoids, pesticides or impurities.
- > Artisanal cannabis-based products are only legal in the UK if they do not exceed a maximum of 0.2% of THC.

Information for patients, carers and the public

> NHS advice on medical cannabis (and cannabis oils) for patients and the public is available from: https://www.nhs.uk/conditions/medical-cannabis/

Further information for healthcare professionals

- VK Medicines Information (UKMi). Cannabidiol oil potential adverse effects and drug interactions. (Published 29th November 2018, updated 13th December 2018): https://www.sps.nhs.uk/articles/cannabidiol-oil-potential-adverse-effects-and-drug-interactions/
- > Royal College of General Practitioners (RCGP). Cannabis-based medicines: an interim desktop guide (November 2018): http://dlc7lpjmvlh0qr.cloudfront.net/uploads/i/v/h/RCGP---Cannabis-based-medication-desktop-guide.pdf

References

- NHS England. Guidance to Clinicians: Cannabis-based products for medicinal use, 31 October 2018. Accessed
 online 13/12/2018: https://www.england.nhs.uk/wp-content/uploads/2018/10/letter-guidance-on-cannabis-based-products-for-medicinal-use..pdf
- British Paediatric Neurology Association. Guidance on the use of cannabis-based products for medicinal use in children and young people with epilepsy, 31 October 2018. Accessed online 13/12/2018: https://bpna.org.uk/userfiles/BPNA CBPM Guidance Oct2018.pdf
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 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/752796/Cannabis Guidance_unlicensed CBPMs Final 311018.pdf
- 4. Association of British Neurologists. Statement on use of marijuana (cannabis) related products in the treatment of complex epilepsies. 15 August 2018. Accessed online 17/12/2018: https://www.theabn.org/media/Documents/ABN%20publications/ABN%20statement%20on%20use%20of%20marijuana%20(cannabis)%20related%20products%20in%20the%20treatment%20of%20complex%20epilepsies%20-%20August%202018.pdf