

Cannabis based medicinal products for use in humans: information for primary care

Key points:

- The legal status of Cannabis based products for medicinal use has been changed from 1st November. These products are now classified as schedule 2 controlled drugs
- Prescribing has been restricted to specialists, on a named patient basis
- Prescriptions cannot be issued by general practitioners in primary care
- Patients should not be referred to specialist doctors for the consideration of medicinal cannabis for the treatment of pain

What are the changes?

- With effect from the 1 November 2018, Cannabis Based Medicinal Products for Use in Humans ("CBPMs") are now listed in Schedule 2 to the 2001 Misuse of drugs regulations.
- 'Cannabis-based medicinal product for medicinal use in human' means a preparation or other product, other than Sativex that:
 - 1.is or contains cannabis, cannabis resin, cannabidiol or a cannabidiol derivative;
 - 2.is produced for medicinal use in humans;
 - 3.is a medicinal product, or a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product.
- All CBPMs apart from Sativex® (listed in Schedule 4 of the MDR and which has a market authorisation) are unlicensed medicines
- For patient access, unlicensed products are considered as 'specials' (i.e. they have no marketing authorisation). This is in line with current practice for other unlicensed medicines
- If a product receives marketing authorisation, all those with the right to prescribe and administer Schedule 2 drugs under the 2001 regulations will be able to do so. No CBPM in schedule 2 currently has marketing authorisation
- Administration by smoking remains prohibited

Who can prescribe cannabis based medicinal products?

- Due to the limited evidence base and their unlicensed nature, the Government has chosen to restrict the decision to prescribe CBPMs to only those clinicians listed on the Specialist Register of the General Medical Council
- As with any unlicensed medicines or "specials", the prescribing of such products must be on a "named patient" basis
- Appendix A contains a flow chart detailing the process for accessing CBPMs
- The current position is that no CBPMs are routinely commissioned by NHS England. When licensed they will become subject to normal NHS appraisal and commissioning processes.
- Currently Trusts are expected to meet the costs of prescribing

Which groups of patients could be prescribed cannabis based medicinal products?

- Longer term guidance is expected from NICE by October 2019, but in the interim NHS England requested guidance from Guidance from the British Paediatric Neurology Association (BPNA) and the Royal College of Physicians (RCP) on the prescribing of CBPMs
- BPNA supports use of these products in two rare forms of childhood epilepsy
- RCP guidance supports prescribing for chemotherapy induced nausea and vomiting only, but not for any form of pain or any other indication
- Patients should not be referred to specialist doctors for the consideration of medicinal cannabis for the treatment of pain

Links to key documents:

Cannabis-based products for medicinal use: Guidance to clinicians

<https://www.england.nhs.uk/publication/cannabis-based-products-for-medicinal-use-guidance-to-clinicians/>

RCP Recommendations on cannabis-based products for medicinal use

<https://www.rcplondon.ac.uk/projects/outputs/recommendations-cannabis-based-products-medicinal-use>

BPNA advice on cannabis based products for medicinal use in children and young people with epilepsy

<https://bpna.org.uk/?page=cmdp>

NHS England patient information leaflet

<https://www.nhs.uk/conditions/medical-cannabis/>

The therapeutic and medicinal benefits of Cannabis based products – a review of recent evidence. Professor Dame Sally Davies Chief Medical Officer for England and Chief Medical Advisor to the UK Government June 2018

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/722010/CMO_Report_Cannabis_Products_Web_Accessible.pdf

MHRA guidance. The supply of unlicensed cannabis-based products for medicinal use in humans

https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials?utm_source=4b3cf7ec-0aad-475f-afba-3372d6084d3e&utm_medium=email&utm_campaign=govuk-notifications&utm_content=immediate

References

- Stakeholder briefing 'Cannabis-based products for medicinal use' – Home office, department of health and social care, MHRA, October 2018
- https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/752796/Cannabis_Guidance_unlicensed_CBPMs_-_Final_311018.pdf
- <https://www.england.nhs.uk/wp-content/uploads/2018/10/letter-guidance-on-cannabis-based-products-for-medicinal-use..pdf>
- <https://www.england.nhs.uk/wp-content/uploads/2018/11/letter-additional-guidance-on-cannabis-based-products-for-medicinal-use.pdf>
- <https://www.chemistanddruggist.co.uk/news/cannabis-derived-medicines-available-prescription-november>

- **Appendix A:** Flow chart detailing the process for accessing CBPMs (copied with thanks from Home office, DHSC and MHRA)

