**Cannabis-based products for medicinal use**

This memo aims to provide a brief overview for the prescribing and supply of cannabis-based products for medicinal use (CBPM) or "medicinal cannabis”. These are broad terms for any cannabis-based medicine used to treat symptoms for certain medical conditions.

**Key points**

* Not all cannabis-based products are legal to possess in the UK.
* CBPMsare schedule 2 CDs and are currently unlicensed medicines – so must be prescribed and supplied in line with the Trust’s unlicensed medicines and controlled drug (CD) processes as well as the MHRA guidance for the prescribing and supply of unlicensed cannabis based products for medicinal use.
* CBPMs can only be prescribed by or under the direction of a doctor on the General Medical Council’s Specialist Register.

**Background Information**

On 1 November 2018 legislation was introduced moving cannabis products from Schedule 1 to Schedule 2 of the Misuse of Drugs Regulations 2001. This allows defined cannabis-based products for medicinal use and restricts routes of access and limits the prescribing of these products to specialist doctors on the GMC’s Specialist Register.

**Types of Cannabis-based product**

There are a wide range of cannabis-based products, with varying constituents including THC and covered by different aspects of legislation. These can be broadly categorised as:

1. **Unlicensed cannabidiol (CBD) products**

There are a range of products marketed as herbal or nutritional supplements. Provided no medicinal claims are made, these products fall outside medicines law.

* Product must not contain THC, which remains a controlled substance.
* *Note:* patients may have bought products which are illegal in the UK over the internet or from non-reputable sources. Any preparations where CBD is not listed or is listed with other cannabis based preparations (e.g. THC) are illegal to possess in the UK.
* [Trust Code of practice for CDs and ward/department CD procedures](http://tww-wafr/WAFR-FAD/Applications/ClinicalGuidance/User/Details.aspx?id=6253) should be followed for any patient being found to be in possession of an illegal CBD or cannabis product.
* CBD oil preparations will be clear in colour
* Herbal preparations are not prescribed within the Trust but are widely available and purchased as over the counter preparations by patients:
* Patient or carer remains responsible for the product and administration of such herbal products. Nursing staff would not be expected to be involved in the administration and/or supply of the product.
* Patients bringing products in with them should make staff aware so that any potential interactions can be considered.

1. **Licensed products/synthetics**

There are a range of cannabis-based products and synthetic products that are already available or being assessed for a marketing authorisation and not affected by the new laws on CBPMs:

* Sativex® - (cannabis extracts containing THC and CBD) is the only licensed cannabis based medicinal product that is available in the UK. It has been authorised by the MHRA as a treatment for spasticity in multiple sclerosis since 2010. Sativex is listed under Schedule 4 of the Misuse of Drugs Regulations 2001 at present. However, Sativex® is currently subject to a NICE ‘do not do’ recommendation: Do not offer Sativex to treat spasticity in people with MS because it is not a cost effective treatment.
* Nabilone - a synthetic, non-natural cannabinoid, is licenced in the UK for use in treatment resistant nausea and vomiting caused by chemotherapy.
* Dronabinol, a synthetic nature-identical, version of THC is listed under Schedule 2 of the Misuse of Drugs Regulations 2001, but it does not have a Market Authorisation from the MHRA in the UK, although it is available internationally. It has been approved by the US Food and Drug Administration (FDA) to treat loss of appetite in people with AIDS, and to treat severe nausea and vomiting caused by cancer chemotherapy in patients with inadequate response to conventional antiemetic treatments.
* Epidiolex® - (pure cannabidiol (CBD)) is approved by the US Food and Drug Administration (FDA) for Lennox-Gastaut Syndrome or Dravet Syndrome in patients 2 years of age and older. This product does not have a UK marketing authorisation, but this is currently being assessed and a decision is expected in early 2019. Meanwhile Epidiolex is available in the UK via the manufacturers Extended Access Scheme and supply as an unlicensed ‘special’.

1. **Cannabis-based products for medicinal use (CBPMs)**

There are three broad requirements that a product should satisfy:

* The product is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative; and
* It is produced for medicinal use in humans; and
* It is a product that is regulated as a medicinal product, or an ingredient of a medicinal product.

The definition is necessarily broad to take account of the range of preparations which are cannabis-based that have been used for therapeutic purposes. This area is still evolving following the changes in the legislation. Product choice, suitability for prescribing and supply arrangements are being put in place nationally.

Currently the only CBPMs are unlicensed medicines. As with prescribing any other unlicensed medicine, it is a clinical decision to determine the most appropriate medication or course of treatment to prescribe for a patient, having taken into account the patient, the clinical condition, the clinical evidence of efficacy and safety and the suitability of licensed medicines.

* CBPMs are schedule 2 CDs and staff must follow all the legal and Trust CD requirements.
* Prescribing is restricted to clinicians listed on the Specialist Register of the General Medical Council (hospital specialist doctors). The decision to prescribe must be in line with guidance from the NHS England and the Trust’s unlicensed medicines and CD processes. Patients and or carers must be involved in the treatment decision.
* Patients should be made aware that the product being prescribed is an unlicensed medicine and a note of this should be included in the patient’s medical records.
* The Trust CD Accountable Officer should be made aware of all prescribing for CBPMs.
* Private prescriptions for CBPMs must meet legal requirements for schedule 2 CDs, be on the specially designated forms (**FP10PCD**) and specify the private prescriber’s six digit identification number.
* There is currently very little domestic availability of these products but pharmacy will be able to advise on available products and routes of supply.
* Patients should be informed that there may be a small delay in obtaining the product as there is a limited number of THC containing products that are available in this country and so may have to be imported and the process for the supply of unlicensed medicines followed.

**Further Resources:**

**NHS England/CMO Letter 31 Oct 2018 and NHS England Addendum Letter 20 November 2018**

<https://www.england.nhs.uk/medicines/support-for-prescribers/cannabis-based-products-for-medicinal-use/>

**NHS Patient Information – 1 Nov 2018**

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

**BPNA Interim Guidance – 31 Oct 2018**

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

**RPC Interim Guidance – 31 Oct 2018**

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

**ABN Interim Guidance – December 2018**

<https://www.theabn.org/media/Documents/ABN%20publications/ABN%20guidelines%20Use%20of%20cannabis-based%20products%20in%20neurology%20December%202018%20v2.pdf>

**MHRA Specials guidance - supply, manufacture, importation and distribution of unlicensed cannabis-based products for medicinal use in humans** <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/752796/Cannabis_Guidance__unlicensed_CBPMs__-_Final_311018.pdf>