December 2018

Position Statement Regarding Cannabis Based Products for Medicinal Use (CBPM) in NHS Grampian – Information for Prescribers

Following a Home Office review regarding the use of cannabis and cannabis-based products for medicinal use (CBPM) the UK government has rescheduled certain CBPMs* through a change in regulations that came into force on 1st November 2018.

The Scottish Government has published guidance for clinicians working in the NHS and in private practice in Scotland regarding CBPM. This includes detailed information regarding the definition of CBPM, who can prescribe such products, the conditions and terms under which prescribing may be considered, controlled drug monitoring and audit requirements.

NHS Grampian will ONLY consider requests to use a CBPM* from a prescriber on the specialist register of the General Medical Council (GMC) where a patient’s clinical circumstances meet ALL of the following criteria (further details and explanation are provided throughout the document):

• For use in one of the specific medical conditions, as detailed below, where there is robust published evidence of benefit or accepted UK guidelines for use
• Where there is an unmet clinical need which cannot be met by a licensed medicinal product
• Where other established treatment options have been exhausted
• Where any specific condition criteria or national guidance has been met.

N.B. NHS Grampian has an established policy for how it considers requests for unlicensed medicines that would apply to any request – a link is provided overleaf.

Medical Conditions
The prescribing of CBPM is only able to be considered for conditions where there is robust published evidence of benefit or accepted UK guidelines for use. Currently this would ONLY include complex intractable epilepsy or chemotherapy induced nausea and vomiting.

The British Paediatric Neurology Association has published guidance regarding the use of CBPM in children and young people with epilepsy. Prescription of a non-licensed cannabis-based product for medicinal use should be used as a treatment of last resort for children who meet all of the following three criteria;

• Have an epilepsy that has proven intractable to treatment with conventional licensed anti-epileptic drugs given at therapeutic doses
• Have not responded to the ketogenic diet or for whom the diet is inappropriate
• Are not candidates for epilepsy surgery.

Royal College of Physicians (RCP) has also published recommendations on CBPM. The RCP does not support the prescribing of CBPM for chronic pain, including
chronic neuropathic pain, as there is insufficient robust evidence to support use. The RCP does not recommend the use of CBPM in palliative care or multiple sclerosis treatments.

GPs should not refer patients with chronic pain, multiple sclerosis or any other conditions not currently recognised as appropriate, to secondary care for CBPM.

Cannabis Based Products for Medicinal Use (CBPM)

Within the regulations there is a clear definition of CBPM. Only such products would be considered for prescribing. A CBPM;

- Is or contains cannabis, cannabis resin, cannabinol or cannabinol derivative
- Is produced for medicinal use in humans AND
- 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.

CBPMs can be classified as naturally occurring or synthetic. Below is a summary of CBPM products currently available:

<table>
<thead>
<tr>
<th>Naturally Occurring CBPMs</th>
<th>Current Licensed Status</th>
<th>CD Status</th>
<th>Indications</th>
<th>Prescribing Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBPMs* e.g. Tilray, Bedrocan products</td>
<td>Unlicensed specials</td>
<td>Schedule 2</td>
<td>Specific medical conditions as detailed below where there is robust published evidence of benefit or accepted UK guidelines for use.</td>
<td>Specialist doctors on GMC specialist register only</td>
</tr>
<tr>
<td>Epidiolex® oral solution</td>
<td>Unlicensed in UK (currently going through licensing process in UK)</td>
<td>Non CD</td>
<td>Lennox-Gastaut Syndrome, Dravet Syndrome</td>
<td>Specialists secondary care</td>
</tr>
<tr>
<td>Sativex®</td>
<td>Licensed</td>
<td>Schedule 4</td>
<td>Sativex® is not recommended for use in NHS in Scotland by the Scottish Medicines Consortium (SMC). <a href="#">SMC Advice</a>. (If accessed privately via private consultant patients will be required to pay for supplies. This will not be transferred to NHS prescription as not approved by SMC).</td>
<td></td>
</tr>
</tbody>
</table>

*These products are affected by the change in regulations and guidance regarding prescribing.*
### Synthetic CBPMs

<table>
<thead>
<tr>
<th>Synthetic CBPMs</th>
<th>Current Licensed Status</th>
<th>CD status</th>
<th>Indications</th>
<th>Prescribing Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dronabinol</td>
<td>Unlicensed in UK</td>
<td>Schedule 2</td>
<td>Nausea, vomiting caused by chemotherapy, unresponsive to conventional anti-emetics</td>
<td>Specialists secondary care</td>
</tr>
<tr>
<td>Nabilone</td>
<td>Licensed</td>
<td>Schedule 2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Synthetic CBPMs have not been affected by the change in regulations.

In the UK, currently all naturally occurring CBPM (excluding Sativex®) are unlicensed medicines. As such, CBPM are unlicensed specials and must be obtained only by suppliers who have the appropriate Medicines and Healthcare Products Regulatory Agency (MHRA) licenses and comply to MHRA standards. As unlicensed products, prescribers take on additional responsibility and liability when prescribing, which will apply to CBPMs.

Products not meeting the definition of CBPM cannot legally be prescribed – this would include unrefined plant materials or cannabis/hemp oils, e.g. products which can be obtained in health food shops or online. These products do not meet the MHRA standards for good manufacturing practice and good distribution practice and are not for medicinal use. These products **should not** be recommended to patients as the strength, quality and contents cannot be guaranteed.

### Prescribing

The current regulations only allow individuals on the specialist register of the General Medical Council (GMC) to prescribe CBPM. This limits prescribing to consultants who must only prescribe within their specialty following the local approval processes. Private and NHS consultants would be expected to follow the same regulations and guidance regarding prescribing of CBPMs.

GPs are not allowed to prescribe CBPM and prescribing must not be transferred from secondary to primary care.

### Referral Process

It would only be appropriate for a patient to be referred to secondary care for consideration of CBPM if they met the criteria regarding the medical condition to be treated. Due to the nature of these conditions it is likely these patients will already have specialist secondary care input.

It is not appropriate for GPs to refer patients to secondary care services for consideration of CBPM for medical conditions not referred to in this guideline.
Approval Processes
NHS Grampian Staff Guidance for Processing Requests to Prescribe Unlicensed, Off-label or Non-formulary Medicines (Including Medicines Awaiting Consideration by, Or Not Recommended For Use By, The Scottish Medicines Consortium must be followed. Form B must be completed and the decision making process follow the Individual Patient Treatment Request (IPTR) framework. In addition to following with IPTR process, as per government requirements final approval must be given by the NHS Grampian Director of Pharmacy or Medical Director for each individual patient treatment plan.

Patient information
NHS Grampian has produced, Information for Patients/Public which contains some of the frequently asked questions regarding the prescribing of cannabis and cannabis related products.

NICE Guidance
The National Institute for Health and Care Excellence (NICE) has been commissioned by the Home Office to produce a clinical guideline on the prescribing of cannabis-based products for medicinal use in humans. This guidance is expected in October 2019. NHS Grampian position statement will be reviewed and amended as necessary following publication and review of NICE guidance and any additional national or Scottish recommendations.

Pharmacy and Medicines Directorate, NHS Grampian