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An Roinn Sláinte
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HSS(MD) 6/2020

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For Action:
Chief Executives of HSC Trusts
GP Medical Advisers, Health and Social Care Board
All General Practitioners and GP Locums (for onward distribution to practice staff)
Director of Integrated Care, Health and Social Care Board
Assistant Director of Pharmacy and Medicines Management, Health and Social Care Board (for onward distribution to Community Pharmacies)

PLEASE SEE ATTACHED FULL CIRCULATION LIST

Dear Colleague

CANNABIS BASED PRODUCTS FOR MEDICINAL USE – UPDATE

Since 1 November 2018 specialist doctors on the Specialist Register of the General Medical Council (GMC) have been able to decide whether to prescribe cannabis-based products for medicinal use where there is an unmet clinical need.

This letter is addressed to those of you who are in the position of deciding whether to prescribe cannabis-based products for medicinal use (CBPM). We appreciate that this comes with challenges. We want to highlight some new resources to support you and remind you of the process for prescribing CBPMs, given that they are almost all unlicensed medicines.

Training for health professionals

NHS England commissioned the University of Birmingham to develop an e-learning module to support health professionals in their discussions with patients and to ensure appropriate access to CBPMs. Healthcare professionals in Northern Ireland are able to access this resource through the Health Education England learning platform, e-learning for health:
https://www.e-lfh.org.uk/programmes/cannabis-based-products-for-medicinal-use/
The e-learning module includes information on the pharmacology of cannabis, legislation governing medical use, therapeutic areas and the evidence available to support the prescription of a CBPM. It will be updated as more information becomes available.

We have also published a set of clinical Frequently Asked Questions (FAQs) on the Department of Health website to provide further support to prescribers, which are available at https://www.health-ni.gov.uk/publications/cannabis-faqs.

Further support for prescribers in the form of the final NICE guideline on Cannabis-Based Medicinal Products, NG144 has been published recently and was formally endorsed by the Department for implementation in Northern Ireland on 14 January 2020. This guideline recommends that nabilone can be considered as an add-on treatment for adults with chemotherapy-induced nausea and vomiting which persists despite optimised conventional antiemetics. The guideline also recommends offering a 4-week trial of THC:CBD spray (Sativex®) to treat moderate to severe spasticity in adults with multiple sclerosis, if other pharmacological treatments for spasticity are not effective.

NICE has also published Technology Appraisals for the use of cannabidiol (Epidyolex®) for severe treatment-resistant epilepsies which were formally endorsed by the Department for implementation in Northern Ireland on 14 January 2020. The appraisals look at the clinical and cost effectiveness of cannabidiol in conjunction with clobazam for adjuvant treatment of seizures associated with Lennox-Gastaut and Dravet syndromes. Both appraisals recommend cannabidiol with clobazam as an option for treating seizures associated with these syndromes in people aged 2 years and older, subject to adequate monitoring and supply arrangements. The Health and Social Care Board (HSCB) will now take steps to ensure timely and equitable access to these treatments in line with extant Managed Entry processes.

Process for prescribing a CBPM

Currently almost all CBPMs prescribed by specialist doctors are unlicensed medicines. GMC guidance states that prescribing of an unlicensed medicine may be necessary where there is no suitably licensed medicine that will meet the patient's need.

Specialist doctors must take into consideration the clinical evidence base, and the guidance from the GMC on licensed, off label and unlicensed medicines and local governance systems when making a decision to prescribe.

Specialist doctors must decide whether it is clinically appropriate to prescribe a CBPM, but it is vital that individual patients or their carers are able to discuss and determine the best treatment for them through shared decision making.

People should be at the centre of decisions about their own treatment and care and as part of this you should explore all treatment options with your patients, along with their risks and benefits. You should discuss the different options available to patients and you should explain and clearly document the rationale for the prescribing decision made by specialist clinicians. As recommended in the NICE guideline on CBPMs, specialists should where available record details of treatment, clinical outcomes and adverse effects using local or national registries as these emerge.

Specialist doctors must also consider local procedures supporting prescribing and funding decisions for unlicensed medicines, such as the Regional Unlicensed Medicines Policy for HSC Trusts. Most procedures will include an application by the

specialist clinician for approval to prescribe to the organisation's Drug and Therapeutics Committee (DTC), or equivalent.

DTCs should assess medicines against the following factors: clinical evidence of efficacy for the specific indication under consideration, patient safety and cost impact. The financial impact of a new unlicensed CBPM should be evaluated and approved in accordance with the local Trust procedure for the introduction of new medicinal products.

There are currently no unlicensed CBPMs which are routinely commissioned for use in Health and Social Care (HSC) in Northern Ireland. As such, HSC Trusts are expected to meet any costs for their patients where there is an unmet clinical need, in line with their normal processes for the use of unlicensed medicines.

Organisations that supply, manufacture, import or distribute unlicensed CBPMs should refer to guidance produced by the Medicines and Healthcare products Regulatory Agency (MHRA) on the supply of unlicensed cannabis-based products for medicinal use in humans to ensure that the prescription of the specialist doctor is fulfilled to the required standards.

Other steps

We hope that this is a useful reminder of the procedure for prescribing CBPMs. This letter is one of several steps we are taking to ensure that patients can access a CBPM where clinically appropriate. The Department is working closely with colleagues in the other UK countries to implement the recommendations from NHS England's report on Barriers to accessing cannabis-based products for medicinal use on NHS prescription for the benefit of patients in Northern Ireland, including establishing a UK-wide paediatric specialist clinical network, clinical trials, and an alternative study for children and young people already in receipt of a CBPM.

Thank you for helping ensure that CBPMs are available and accessible to the right patients at the right time to achieve optimal outcomes.

Yours sincerely

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Chief Medical Officer

MRS CATHY HARRISON
Chief Pharmaceutical Officer

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This letter is available on the Department of Health website at https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications

Annex 1

Factors to take account of when considering a prescription of an unlicensed CBPM

Factors to consider	Supporting advice, resources and examples
Prescribing doctor	
• **As outlined by government regulation the decision to prescribe CBPMs is restricted to specialist doctor on the Specialist Register of the General Medical Council (GMC).** • **Doctors 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.** • **For any licensed products this will be defined by the Marketing Authorisation, e.g. Sativex® should be initiated and supervised by a doctor with specialist expertise in treating patients with Multiple Sclerosis (MS)** • **To ensure appropriate safeguards and monitoring in the first instance it is recommended that specialist prescribing only is most appropriate rather than a shared care arrangement.**	• Discussion with a peer clinician in the same Specialist Register of the GMC is strongly advised. • Any recommendations for the prescribing doctor do not remove or replace the clinical discretion of the prescriber in accordance with their professional duties. • Local medicines governance systems for unlicensed medicines should be taken account of, with further advice sought locally from the local hospital Chief Pharmacist/Director of Pharmacy where required. • HSC prescribers should be aware of their responsibilities as outlined in the Regional Unlicensed Medicines Policy and associated appendices. • As a minimum, approval to prescribe should be granted by Drug and Therapeutics Committee Chair or Trust Medical Director. • Circular HSS(MD)16/2003: Regional Group for Specialist Medicines Criteria for Red / Amber List products
Evidence base and clinical guidelines	
• **CBPMs should only be prescribed for indications where there is clear published evidence of benefit or UK guidelines and in patients where there is a clinical need that cannot be met by a licensed medicine or where established treatment options have been exhausted.** • **Prescribers and approvers must be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy.**	• Circular HSS(MD) 28/2018: Cannabis-based products for medicinal use • GMC guidance on prescribing unlicensed medicines. • MHRA guidance on off-label or unlicensed use of medicines: prescribers' responsibilities • Royal College of Physicians guidance focused on prescribing of CBPMs for medicinal use in chemotherapy induced nausea and vomiting, chronic pain and pain in palliative care.

	• British Paediatric Neurology Association guidance on the use of CBPMs in children and young people with epilepsy. • Association of British Neurologists interim guidance on the use of CBPMs in adult neurological conditions such as MS • NICE guidance on CBPMs published in November 2019.
Shared decision making	
• **Working closely with individual patients and their carers (where appropriate) to agree the best treatment, taking into account the clinical evidence base, clinical trials that may be available and the patients' individual clinical circumstances.** • **Ensuring appropriate information is available to patients and their carers.**	• NICE statement on shared decision making • Northern Ireland Medicines Optimisation Quality Framework: Standard 1 Safer Prescribing with Patient Involvement • NI Direct patient information on Medicinal cannabis (and cannabis oils), • Department for Transport advice for healthcare professionals on drug driving and medicine. • Northern Ireland Clinical Trials Unit information for patients on clinical trial participation
Product quality and supply	
• **For unlicensed products prescribers and approvers must be confident that any products prescribed are in line with MHRA specials advice on supply, manufacture, importation and distribution, to ensure acceptable product content and quality.** • **MHRA quality checklists should be followed at each stage of the prescription process to ensure that the prescription of the specialist doctor is fulfilled.**	• Medicines and Healthcare products Regulatory Agency (MHRA) specials guidance on cannabis. • MHRA flow chart and quality checklists on the process for prescribing, supplying and importing CBPMs e.g. content of cannabinoid constituents (i.e. THC/CBD) must be declared on the product label.
Monitoring and safeguards	
• **Local protocols on controlled drugs must be followed if appropriate, including any additional specific local governance for CBPMs.** • **Treating clinicians must make a clear, accurate and legible record of all medicines prescribed and, where common practice is not being followed the reasons for prescribing an**	• Advice from the Controlled Drug Accountable Officer (CDAO) and the local medication safety officer should be sought if required. • GMC guidance on prescribing unlicensed medicines. • MHRA Yellow card scheme for reporting suspected adverse reactions

unlicensed medicine must be clearly documented. These records must be auditable. • **Prescribers must take responsibility for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so.** • **To maintain effective pharmacovigilance a detailed assessment of clinical and patient outcome measures should be maintained.** • **All suspected adverse reactions to both licensed and unlicensed products must be reported to the MHRAs Yellow card scheme. For clinical trials these must be reported as per clinical trial protocol.**	