31 October 2019

Interim policy position on cannabis-based medicinal products

Introduction

In November 2018, the law changed to allow cannabis-based medicinal products to become Schedule 2 controlled drugs under the Misuse of Drugs Regulations 2001, making them available on prescription.

Most cannabis-based medicinal products are unlicensed medicines in the UK, apart from some products with a marketing authorisation, which are licensed for certain conditions.

Although many medicines prescribed in the NHS are unlicensed, particularly those prescribed for children, treating patients with unlicensed medicines poses a higher risk than with a licensed medicine as they may not have been assessed for safety, quality and efficacy. A patient may only be prescribed an unlicensed cannabis-based medicinal product to treat an appropriate health condition if a referral is made to a relevant specialist doctor. The prescribing restrictions set out in regulations also ensure that access to these medicines is available to patients with clinical needs that cannot be met by licensed medicines, while minimising the risks of misuse, harm and diversion.

Unlicensed cannabis-based medicinal products can **only** be prescribed by a specialist doctor on the General Medical Council's Specialist Register. However, licensed products can be prescribed by any practitioner with the authority to do so under the 2001 Regulations.

Draft guidance from NICE and a review by NHS England have highlighted a need for more research on cannabis-based medicinal products. In the interim, we are setting out what is required for providers registered with CQC and prospective registrants.

Please see Regulation 16A of the Misuse of Drugs Regulations 2001 for further information on order, supply and use of cannabis-based medicinal products.

Our interim position does not cover cannabidiol (CBD) 'oil' products sold most commonly as food supplements. These are available from a variety of outlets in the UK and their status is currently being reviewed by the Food Standards Agency. They cannot make health claims, and would need to satisfy the 'Exempt Product' criteria as set out in the Misuse of Drugs Regulations 2001 (see the Home Office factsheet Cannabis, CBD and other cannabinoids). Products that make medicinal claims would be regarded as medicines by the Medicines and Healthcare products Regulatory Agency (MHRA Guidance Note 8, appendix 10).

Requirements for registration with CQC

Although the number of prescriptions for cannabis-based medicinal products is currently very small, we are aware of some prescribing in the NHS, and of clinics being set up in the independent sector. This interim policy position sets out CQC's requirements for registered providers and prospective registrants. See more about the process and requirements for registration with CQC.

Specialist doctors who work in independent healthcare must register with CQC for the regulated activity of *treatment of disease, disorder and injury.* If they intend to prescribe and treat patients with cannabis-based medicinal products, they must be able to demonstrate that they have assurances in place to deliver safe and effective care in line with relevant legislation and guidance.* As well as taking responsibility for prescribing the medicine, this includes overseeing an individual patient's care and any follow-up treatment or arranging for another suitable doctor to do so. It also includes ongoing monitoring of the effectiveness and side-effects of the prescribed medicine, and keeping clear, accurate and legible records of all medicines prescribed and where common practice is not being followed. There should also be regular overview and auditing of all prescribing of cannabis-based medicinal products by clinicians at the service.

Our inspections will cover any specialist doctor in the NHS or an independent healthcare service who intends to prescribe cannabis-based medicinal products. Some independent doctors are exempt from CQC registration.

Using our key lines of enquiry (KLOEs), we expect to see the following:

Safe prescribing (KLOE S4)
Prescribing and clinical restrictions for cannabis-based medicinal products should not differ between NHS and non-NHS settings, and only doctors on the General Medical Council (GMC) Specialist Register may prescribe them. As with all areas of clinical care, these doctors must work within the limits of their competence (non-medical prescribers cannot currently prescribe cannabis-based medicinal products). As stated in the GMC guidance, unlicensed medicines should not be used as first line treatments to meet a patient's needs.

Doctors on the GMC Specialist Register can prescribe cannabis-based medicinal products for unmet clinical need on a named patient basis. In an NHS setting, this would need to be approved by the chair of their trust's drug and therapeutic committee or the trust's medical director. In non-NHS settings, prescribers are expected to follow an equivalent but proportionate process, for example, through decisions made by a clinical governance board or similar.

However, **the decision to prescribe is ultimately one for the prescribing clinician**. This must be within their own area of practice and training (for example, physicians for adults should not be prescribing for children), and must be based on sufficient knowledge of the patient and their previous medical history.

* The Misuse of Drugs Regulations 2001, Health and Social Care Act 2008, Care Quality Commission (Registration) Regulations 2009

Informed consent (KLOE E6)
As with any other unlicensed medicine, determining the most appropriate medicine or course of treatment to prescribe for a patient is a clinical decision. This should take into account the preferences and choices of the patient (or their parents or carers), their clinical condition, the clinical evidence of efficacy and safety, and the availability of licensed medicines. Currently, there is a lack of evidence on the long-term safety and effectiveness of cannabis-based medicinal products, and clinicians will be required to justify prescribing them. As an example, an organisation may be participating in an approved clinical trial or in cases where there are no suitable licensed medicines that meet the patient's needs. Clinicians must also record discussions and give patients, their parents or carers sufficient information about the medicine to allow them to make an informed decision.

Evidence of effectiveness (KLOE E1)
All prescribers should be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy and they should follow available clinical guidelines and principles for prescribing cannabis-based medicinal products. Guidance from NICE is due to be published in November 2019. We are also aware of research evidence and guidance from international bodies (such as the European Medicines Agency) and interim guidance from professional organisations (such as the Royal College of Physicians, the British Paediatric Neurology Association and the Association of British Neurologists).

Although the guidance provides recommendations for some treatment options with cannabis-based medicinal products, it is not a prescribing protocol, and the responsibility for the prescribing decision remains with the prescriber, in consultation with the patient or their parent or carer. Where a prescriber takes a different approach from that set out in national guidance, clinicians and service providers need to provide a clear rationale to explain the decision to prescribe. A good practice example of this would be shared clinical decision-making with a colleague who is another specialist with an appropriate scope of practice who does not have a pecuniary interest in making a positive decision to treat.

We will continue to be informed by national guidance and will review this interim policy position in six months.

Further guidance and information:

- The Misuse of Drugs (amendments) (cannabis and licence fees) (England, Wales and Scotland) Regulations 2018
- The Misuse of Drugs Regulations 2001
- NICE: Cannabis-based medicinal products
- NHS England: Cannabis-based products for medicinal use
- Royal College of Physicians London: Recommendations on cannabis-based products for medicinal use
- General Medical Council: Information for doctors on Cannabis-based products for medicinal use and Prescribing unlicensed medicines

- Medicines and Healthcare products Regulatory Agency: The supply, manufacture, importation and distribution of unlicensed cannabis-based products for medicinal use in humans 'specials'
- Medicines and Healthcare products Regulatory Agency: Guidance note 8.
- Care Quality Commission: CQC's role in the safer management of controlled drugs.