**THE NICE GUIDELINE ON MEDICINAL CANNABIS:**

**KEEPING PANDORA’S BOX SHUT TIGHT?**

**ABSTRACT**

November 2018 saw the prescription of unlicensed medicinal cannabis products being legalised in the UK, accompanied by loud media fanfare. One year on, it seems that access to medicinal cannabis in this country continues to be extremely rare, raising questions about what might be stopping doctors from making use of the legal space to prescribe. This commentary explores some of these questions, outlining the theoretical space for legal prescribing and examining whether the recently announced NICE guideline does anything to ease the deadlock.

Keywords – cannabis – guideline - legalisation - medicines - NICE - prescribing

**INTRODUCTION**

The prescription of unlicensed ‘Cannabis Products for Medicinal Use’[[1]](#footnote-1) was legalised in the UK in November 2018.This was achieved by rescheduling ‘Cannabis Products for Medicinal Use by Humans’ (CPMs) under the Misuse of Drugs Regulations 2001, moving them from Schedule 1 (controlled drugs considered to have no medicinal value) to Schedule 2 (controlled drugs acknowledged to have medicinal benefits).[[2]](#footnote-2) The reform enabled investigation of these products via clinical trials[[3]](#footnote-3) (previously breaching criminal law) and opened a theoretical space for doctors to prescribe these drugs, albeit currently stifled by practical and legal obstacles and medico-legal concerns.

**I. THE ROAD TO LEGALISATION – A MEDICALISED APPROACH?**

Critical in the process of legal reform were the experiences of Alfie Dingley and Billy Caldwell, children suffering from rare, treatment-resistant forms of epilepsy. Both children’s parents, amongst others, campaigned tirelessly to pave the way for their children to have access to medicinal cannabis without breaking the law.[[4]](#footnote-4) But it was the announcement of Dame Sally Davies, then Chief Medical Officer, in June 2018, that there was ‘conclusive evidence of the therapeutic benefit of cannabis based medicinal products for certain medical conditions and reasonable evidence of therapeutic benefit in several other medical conditions’ which finally opened the door to liberalisation.[[5]](#footnote-5)

However, in March 2019, Dame Davies observed that the reforms had opened a ’Pandora’s box’[[6]](#footnote-6) – the near panacea of asserted medicinal possibilities, alongside media trumpeting of ‘legalisation’ had generated unrealistic expectations of access on the part of patients, which were unlikely to be met until randomised controlled trials had been completed. Certainly, the list of potential therapeutic applications for cannabis and its derivatives is staggering. These drugs are reported as having medicinal value for patients with intractable epilepsy, nausea/vomiting caused by chemotherapy, spasticity in multiple sclerosis, chronic pain, fibromyalgia, anxiety and depression, the rigidity and tremors associated with Parkinson’s disease, Alzheimer’s disease, chronic fatigue syndrome, cancer and the distress experienced by patients receiving palliative care, amongst other conditions. The multitude of therapeutic applications is thought to be attributable to the 100+ constituents of the plant with known or suspected effects on the body’s natural endocannabinoid system which pervades the human anatomy.[[7]](#footnote-7)

Whatever the true therapeutic range of medicinal cannabis is, we do know that cannabis derived drugs can be life-saving.[[8]](#footnote-8) Where found to be safe and effective they may also have the potential to reduce pain and suffering associated with many conditions, whilst simultaneously releasing patients from the serious side effects associated with conventional treatments.[[9]](#footnote-9) There have been indications from other jurisdictions that legalisation of cannabis use (medicinal *or* recreational) was followed by a reduction in morbidity related to opioid use.[[10]](#footnote-10) In addition to direct quality of life improvements for many patients and their families, it is entirely plausible that, in time, conversion to medicinal cannabis could have cost savings for an over-stretched and under-resourced National Health Service (NHS).[[11]](#footnote-11) These savings could take the form of reduced prescriptions of other expensive therapies[[12]](#footnote-12) and reduced hospitalisation of patients with chronic conditions.

**II. A TWO-TIER SYSTEM?**

Despite legalisation, many patients who could potentially benefit from cannabis products have been unable to access these drugs, whether through the NHS or privately. It appears that a two-tier system is in operation, with access being determined by ability to pay. At the time of writing it is thought that there have been around 20 prescriptions for medicinal cannabis in the UK on the NHS since legalisation in November 2018.[[13]](#footnote-13) Even then, prescription rates in the private sector are extremely low, and the cost remains prohibitive, with a number of the families concerned facing financial hardship to provide a life-changing drug at a cost of £800 to £1500 per month for their loved ones.

So why are doctors not prescribing? A number of factors collectively impede access to medicinal cannabis; the relative absence of good quality, randomised controlled trial data[[14]](#footnote-14), the narrowly drawn practice guidance, uneven distribution of knowledge relating to cannabis products and their effects (the endocannabinoid system is not currently taught on many medical school curricula), stigma surrounding these drugs and medico-legal defensiveness amongst doctors, compounded by uncertainty about their indemnity position. In addition to these constraints, the administrative burdens for a doctor arranging a prescription are extremely daunting. As things stand, despite the UK being one of the world’s largest exporters of cannabis for medical use,[[15]](#footnote-15) unlicensed CPMs fall under the Medicine and Healthcare Products Regulatory Agency’s (MHRA) ‘specials’ regime.[[16]](#footnote-16) Accordingly, these products can only be imported on a ‘patient by patient basis’ and subject to a number of other strict regulatory requirements.[[17]](#footnote-17) Each new prescription requires a special Home Office licence[[18]](#footnote-18) to import the product from an EU Good Medical Practice approved supplier, and this adds a significant uplift to the cost.

Medical societies have cautioned against prescribing whilst the legalisation of randomised controlled trials is exploited, but it could take years for the anticipated high-quality data to emerge. In the meantime, innovative prescribing could be one of the keys to unlocking parts of this sequential puzzle – in time it will help to normalise CPMs as part of a clinician’s toolbox, reduce stigma for both doctors and their patients, generate experience which can be shared with other clinicians and produce data which will expand the knowledge base, whilst also assuring industry that there is a UK market worth investing in, consequently bringing down the price[[19]](#footnote-19). This commentary will examine some of the implications of the recent National Institute for Health and Care Excellence (NICE) guideline within the current regulatory framework and ask to what extent it facilitates that process and indeed encourages innovative prescribing in this field of medicine.

**III. NICE GUIDELINE: BALANCING BENEFITS, COSTS, NEED AND INNOVATION?**

NICE issues recommendations on pharmaceutical products based on a review of their safety, efficacy and cost-effectiveness. In exercising this function, it must ‘have regard to’ the broad balance between the benefits and costs of health service provision, the degree of need of persons for health services or social care in England, and the desirability of promoting innovation.[[20]](#footnote-20) The NICE guideline on *Cannabis Based Medicinal Products* (CBMPs[[21]](#footnote-21)) was published in November 2019[[22]](#footnote-22) and, whilst it endorses the therapeutic value of CBMPs for some conditions, it does so in very narrow terms, namely in the case of three licensed products.

The guideline covers applications of CBMPs in four conditions: 1) spasticity in adults with multiple sclerosis, 2) intractable nausea and vomiting caused by chemotherapy in adults, 3) severe treatment-resistant epilepsy and 4) chronic pain:

* in respect of cases of *spasticity in multiple sclerosis*, prescribers should ‘offer’ a four-week trial of tetrahydrocannabinol (THC): cannabidiol (CBD) spray, to be continued if the patient reports a 20% reduction in spasticity.[[23]](#footnote-23)
* NICE has recommended the use of cannabidiol as an ‘adjunctive therapy’ with clobazam, as an option for the treatment of two rare forms of *treatment-resistant epilepsy*, Lennox-Gestaut Syndrome and Dravet’s Syndrome only.[[24]](#footnote-24)
* For *adults with intractable nausea/vomiting associated with chemotherapy*, prescribers should ‘consider’ nabilone – the word ‘consider’ here indicates that in NICE’s view there is a closer balance between benefits and harms.[[25]](#footnote-25)
* In cases of *chronic pain*, the guideline adopts the more prescriptive tone of ‘Do not offer’ nabilone, drabilone, THC or CBD with THC[[26]](#footnote-26) and ‘Do not offer’ CBD for chronic pain in adults, unless as part of a controlled trial.[[27]](#footnote-27) Whilst prescribers in many countries clearly do prescribe medicinal cannabis for chronic pain[[28]](#footnote-28), NICE steers prescribers away from considering this option. The recommendation regarding chronic pain was based on there being ‘some evidence’ of ‘modest’ effectiveness, but given the large number of people who might benefit, medicinal cannabis was not cost effective as a treatment option.[[29]](#footnote-29) Presumably where, as in the case of chronic pain, a guideline is based largely on cost effectiveness rather than safety concerns, the impact of NICE guidance on private prescribing could be markedly lower.

Whilst the recommendations in relation to spasticity and epilepsy represent an advance on the draft guideline published earlier in the year[[30]](#footnote-30), they are small increments of liberalisation, notably restricted to drugs already licensed for those uses in the UK: nabilone, ‘Epidyolex’ and ‘Sativex’.[[31]](#footnote-31) Prescribing beyond the terms of the guideline can be regarded as an example of medical innovation, which, with appropriate attention to safeguarding a patient’s interests, can be entirely consistent with a doctor’s duties.[[32]](#footnote-32) The legal space within which to prescribe currently unlicensed CBMPs, or prescribe licensed CBMPs ‘off-label’[[33]](#footnote-33) (e.g. prescribing Sativex for chronic pain[[34]](#footnote-34) or Epidyolex for other types of epilepsy) is an example of an innovative therapeutic option, but there are fears that the guideline will merely serve to sustain the deadlock around CBMP prescribing.

***Facilitating or Paralysing Innovative Prescribing?***

The precise status and impact of NICE guidance on prescribing practices generally, or in this context, is unclear - much depends on how doctors engage with it.[[35]](#footnote-35) On the one hand, NICE guidelines are widely perceived as constraining clinical freedom,[[36]](#footnote-36) and NICE recognises that the wording of its guideline on CBMPs and ‘chronic pain’ is likely to have a chilling effect on prescriptions in this area.[[37]](#footnote-37) Defensive approaches to doctoring may rule out even considering prescribing medicinal cannabis, except (perhaps) in situations which fall squarely within the NICE recommendation, due to a fear that departing from the guideline will invite the possibility of challenge, complaint or litigation. Guidance issued by professional bodies only amplifies these concerns, repeating with mantra-like frequency, ‘the responsibility of prescribing a (cannabis product) will remain with the prescribing clinician’ with no further explanation of what this means.[[38]](#footnote-38) NICE guidance is in effect the conduit through which NHS prescriptions of cannabis products might be reliably accessed, but it also has an impact on private practice because of its relationship with the standard of care. Although we know little about practitioner application of NICE guidelines, we do know they are used by lawyers in negligence litigation.[[39]](#footnote-39) They are often observed as part of the claimant’s narrative that there was a failure to ‘comply’ with the guideline and that this is indicative of a finding of negligence. Doctors may harbour concerns that if trial of a cannabis product with a patient results in unanticipated side effects, the patient may weaponise departure from the NICE guideline to bolster an allegation of negligence or impaired fitness to practice.[[40]](#footnote-40)

However, guidance does not take the place of clinical judgement in relation to individual patients[[41]](#footnote-41) and the NICE guidelines explicitly remind practitioners that they are ‘not mandatory’.[[42]](#footnote-42) Recent court judgments consistently emphasise that NICE guidance and the clinician’s standard of care are not coextensive. In *Darnley v Croydon* *Services NHS Trust*, Robinson J regarded the argument that failing to meet a NICE guideline on target waiting times in A&E represented suboptimal care and therefore negligence, as ‘superficially attractive’ whilst observing that ‘the real world is not so simple.’[[43]](#footnote-43) In *Price v Cwm Taf[[44]](#footnote-44)*, the claimant similarly failed to persuade the court to view a departure from NICE guidelines as ‘prima facie negligence,’ the judge preferring to say that:

‘a clinical decision which departs from the NICE Guidelines is likely to call for an explanation of some sort. The nature and degree of detail required will depend on all the circumstances.’[[45]](#footnote-45)

Attempts to argue that departures from NICE guidelines ought to be disclosed to the patient as part of the duty to ensure patients are giving informed consent[[46]](#footnote-46) have also failed. Justice Robinson acknowledged that whilst there was a public law duty on a Clinical Commissioning Group to provide clear reasons for not following NICE guidelines,[[47]](#footnote-47) there was no universal duty to inform the patient that their treatment involved a departure from NICE guidelines.[[48]](#footnote-48)

It is therefore clear that departing from the recent guideline is not to be equated with negligence, however, clinicians prescribing beyond NICE recommendations should certainly be advised to document their rationale for prescribing in detail[[49]](#footnote-49), and generally ‘safety net’ even more assiduously than usual, including when researching possible contraindications, taking detailed histories from their patients, consulting and taking account of the views of other doctors[[50]](#footnote-50) and recording the results of this, and taking time over obtaining the informed consent of their patients, so as to be able to justify their decision on clinical grounds.

***‘Shared Care Arrangements’: Softening the Requirement of Specialist Prescribing?***

One aspect of the NICE guideline which is marginally conducive to enabling access to these drugs relates to the issue of ‘who’ can prescribe. Most CBMPs remain ‘unlicensed’ (i.e. without a market authorisation) and the 2018 regulations require that the *initial* prescription of these unlicensed drugs must be by specialists listed on the Specialist Register of the General Medical Council with a specialist interest in the condition being treated.[[51]](#footnote-51) The majority of patients do not have direct access to specialists and will need a referral from a GP in order to access a specialist who could lawfully prescribe. The GP therefore has once again been gifted with an additional, probably unwelcome, ‘gatekeeper’ role[[52]](#footnote-52) and the patient seeking access to medicinal cannabis is faced with needing in effect two approvals before being considered for a prescription. Even though the prescribing itself is done by another clinician who must form their own view as to the appropriateness of that prescription, and the cost may not be directly borne by the NHS if the patient is paying privately, it is quite possible that many GPs will be reluctant to sanction a referral knowing it is for access to medicinal cannabis.[[53]](#footnote-53)

Interim guidance from a number of professional bodies also applies a very narrow interpretation of the 2018 regulations, assuming that the act of prescribing unlicensed CBMPs was always to be reserved for specialists,[[54]](#footnote-54) despite the wording of the regulation stating merely that the product must be ‘for use in accordance with *a prescription or direction of* a specialist medical practitioner.’[[55]](#footnote-55) Whilst NICE envisages prescription of CBMPs in very narrow circumstances, it adopts a slightly more positive interpretation of the rules on who can prescribe, providing guidance on how a ‘shared care arrangement’ might work in this setting.[[56]](#footnote-56) For advocates of better access to medicinal cannabis products, this is encouraging and could be a first step towards GP prescribing. Under shared care, a patient who is doing well under a prescription of CBMPs may seek access to follow up services, including monitoring appointments or even further prescription, under the direction of the initial prescriber, but locally with their GP.[[57]](#footnote-57) We do not yet know how receptive GPs might be to shared care arrangements, particularly if that shared care straddles private healthcare (the specialist) and NHS provision (the GP). Obviously, such an arrangement would be at a cost to the NHS and potentially expose the GP to liability in a field of medicine they are not familiar with. They may also anticipate disapproval from peers for involving their immediate colleagues in a process which still undoubtedly carries the stigma of a previously criminalised recreational drug.[[58]](#footnote-58)

***The Inexperienced Doctor and the Expert Patient: Montgomery v Lanarkshire in Action?***

Unlicensed CBMPs are distinct from most innovative therapies, not least because doctors are very likely to encounter experienced patients having used cannabis medicinally, perhaps through lawful prescription in another country or having self-medicated using home cultivated strains or supplies from the black market. NICE guidance so far says little about navigating this space in which an experienced adult patient meets a clinician with relatively little experience of CBMPs. There is an argument for saying that prior patient experience should be capable of trumping the lengthy ‘last resort’ approach recommended in much professional guidance on the issue.[[59]](#footnote-59) Reluctance to seriously consider the use of medicinal cannabis products can be regarded as an affront to the prudent adult patient, who is increasingly being urged to take responsibility for their own healthcare decision making,[[60]](#footnote-60) and has been argued to be in contravention of the human right to health.[[61]](#footnote-61) In light of this, the messaging from the NHS seems inappropriate: hospital doctors might consider prescribing in cases of serious epilepsy in children, spasticity in MS, vomiting or nausea from chemotherapy, but ‘[i]f the above does not apply to you, *do not ask your GP for a referral for medical cannabis.*’[[62]](#footnote-62) This crude attempt to manage patient expectations feels heavy handed - why should a knowledgeable patient not ask for a referral? This unique profile of patient requires a different approach, not easily accommodated within the terms of the NICE guidance.

If the effect of the proliferation of guidelines and the recent NICE guideline is to effectively rule out patients trying these medicines when there are good clinical reasons for thinking they may be of benefit (published evidence beyond RCTs, clinician experience and patient experience), this raises serious questions about the constraint of clinical autonomy, and the pursuit of what is in the patient’s best interests. There is certainly a tension between such an approach and the conceptualisation of healthcare in the Supreme Court judgment of *Montgomery v Lanarkshire Health Board* which advocates a partnership between doctor and patient, treating patients as:

‘capable of understanding that medical treatment is uncertain of success, and may involve risks, accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices.’[[63]](#footnote-63)

There is understandable concern that patients trying an unlicensed medicine raise particular issues in terms of obtaining informed consent, which remain problematic in the case of informed and experienced patients. For example, such patients could be affected by ‘optimism bias’ based on their previous experience, which may not be replicated by the doctor’s prescription. In such situations as with any innovative medicine, it is probably best to ensure ‘that the patient realises s/he is effectively rolling the dice’ as the risks cannot be clearly defined.[[64]](#footnote-64) It will also be important to ensure that the patient knows that the drug may take some months to work, that current arrangements mean there may be a break in supply, and that the drug may not work at all, so that the patient is prepared for disappointment. But these are not reasons to avoid prescribing, they are reasons for due diligence.

The practice of prescribing is subject to detailed guidance from the General Medical Council (GMC) which arguably does leave room for considering the prior experiences of the patient.[[65]](#footnote-65) There is a general duty to prescribe only where the doctor has ‘adequate knowledge of the patient’s health’ and where ‘satisfied that they (the drugs) serve the patient’s needs.’[[66]](#footnote-66) Specific provisions relating to the prescription of *unlicensed* medicines, include that doctors should only prescribe where ‘on the basis of an assessment of the individual patient, you conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient.’[[67]](#footnote-67) The GMC explicitly states that ‘necessity’ here does not necessarily require an application of evidence-based medicine based solely on published studies and meta-analyses of the efficacy and safety of these drugs. The guidance endorses the use of ‘evidence’ alongside ‘experience of using the medicine’ to demonstrate its safety and efficacy.[[68]](#footnote-68) The meaning of ‘experience’ here is not explained, but could be interpreted to mean the patient’s own experience of using cannabis, experiential case studies which are published in the medical literature, ‘N of 1’ studies (which are clinical trials involving one participant)[[69]](#footnote-69), or the doctor’s own experience of prescribing this particular drug for this particular condition. We know that this reference to ‘experience’ cannot be simply to the doctor’s own clinical experience, as this would beg the question of how a doctor could acquire such experience if other forms of experience cannot be used to justify use of the medicine.

The NICE guideline also includes a possible nod to patient experience in a section headed ‘factors to consider when prescribing.’ The text indicates merely that ’current and past use of cannabis’ should be taken into account[[70]](#footnote-70), but this is alongside a list of what might be regarded as contraindications, and nothing is said about treating a patient who brings extensive experience with them of using cannabis as medicine. Doctors will need more support and advice in negotiating this difficult terrain and taking into account patient experience where relevant, given the challenges this poses to medicalised models of ‘evidence.’

**CONCLUSION**

Legal reform is frequently an essential but insufficient mechanism for engineering change. The experience of ‘legalisation’ of medicinal cannabis followed by relative inaccessibility is shared with a number of other countries,[[71]](#footnote-71) and a great deal can be learned by looking to the positive trajectory of increased access in, for example, Canada and Australia, and how this has been achieved.[[72]](#footnote-72) Doctors are likely to be concerned that if they prescribe an unlicensed medicinal cannabis product (or even merely refer a patient to a specialist who might provide that prescription), they may be regarded as in breach of their professional duties. Despite a proliferation of recent guidance in the UK, further advice and education is needed to support doctors in this difficult but promising area of medicine. Clinical and patient activism, in the prelude to high quality RCTs, will likely play a significant part in the uptake of prescription in the future.

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1. Cannabidiol (CBD) products not containing Tetrahidrocanabinol (THC) at quantities of >0.2% are not controlled drugs under the Misuse of Drugs Act 1971 and are not caught by the regulation, but are treated as food supplements, not sold for medicinal use: *Barriers to accessing cannabis-based products for medicinal use on NHS prescription* (NHS England, 2019)at para 11. [↑](#footnote-ref-1)
2. Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (E.W.&S) Regulations 2018 (SI 2018 No.1055) inserting a new Regulation 16A into the Misuse of Drugs Regulations 2001 (SI 2001/3998). [↑](#footnote-ref-2)
3. E.g. ‘Project Twenty21’ set up by DrugScience - <https://drugscience.org.uk/project-twenty21/>. [↑](#footnote-ref-3)
4. # ‘Medicinal cannabis: how two heart breaking cases helped change the law,’ *The Guardian* 26th July 2018.

   [↑](#footnote-ref-4)
5. *The therapeutic and medicinal benefits of cannabis based products – a review of recent evidence* (June, 2018) at 1.4. [↑](#footnote-ref-5)
6. Giving evidence to the House of Commons Health and Social Care Committee, *Drugs Policy.* March 2019. [↑](#footnote-ref-6)
7. See R. Pertwee, ‘Cannabinoid pharmacology: the first 66 years’ (2006) 147(1) *Brit Journal of Pharmacology* 163. [↑](#footnote-ref-7)
8. E.g. Dravet’s syndrome where there is a substantial risk of a fatal seizure under 10 years of age: *Barriers to accessing cannabis-based products for medicinal use on NHS prescription* (NHS England, 2019) p.10. [↑](#footnote-ref-8)
9. E.g. opioids, non-steroidal anti-inflammatory drugs (NSAIDs), Disease Modifying Antirheumatic Drugs (DMARDs). Side effects can include, for example: nausea, vomiting, physical dependence, respiratory depression (opioids); stomach ulcers, increased risk of renal failure, increased risk of stroke, allergic reaction, ringing in the ears (NSAIDs); liver problems, immune system deficiency (DMARDs). [↑](#footnote-ref-9)
10. Y. Shi, ‘Medical marijuana policies and hospitalizations related to marijuana and opioid pain reliever’ (2017) 173 *Drug and Alcohol Dependence* 144. The opioid epidemic in the UK is of great concern, albeit not yet considered to be of the scale of an opioid crisis as in the US and prescriptions of opioids has reduced slightly since 2016: see *Prescribed Medicines Review* (Public Health England, September 2019). [↑](#footnote-ref-10)
11. See the report on Lucy Stafford’s experience in ‘Medical Cannabis: Why are Doctors Still Not Prescribing It?’ *The Guardian* 3rd November 2019 – estimated as saving the NHS approximately £5,000 per month (albeit at a personal cost of £800 per month). [↑](#footnote-ref-11)
12. V. Carrieri et al, *Do-It-Yourself medicine? The impact of light cannabis liberalization on prescription drugs* (University of York WP 19/07) – based on the experience in Italy. [↑](#footnote-ref-12)
13. *inews* 14th November 2019. Available at https://inews.co.uk/news/health/medicinal-cannabis-nhs-prescriptions-change-law-996344. This does not include patients who may have accessed drugs through Compassionate Use /early access schemes: *Barriers* ibid (n.8)*.* Although there are different views on the position here – e.g. the Care Quality Commission reported in October 2019 that there has been ‘some prescribing on the NHS’ (*Interim policy position on cannabis-based medicinal products* (CQC, 2019). [↑](#footnote-ref-13)
14. *Barriers* (n.8) at para 23. [↑](#footnote-ref-14)
15. *The UN International Narcotics Control Board: Annual Report for 2017* (2017) records that in 2016, the UK was the largest producer of cannabis for medicinal use (95 tonnes), at 44. [↑](#footnote-ref-15)
16. Regulation 167 of the Human Medicines Regulations 2012 (SI 2012/1916) - allowing the import of unlicensed medicines on a named patient basis as ‘specials’. This does not affect products with a marketing authorisation, e.g. nabilone, Epidyolex and Sativex. [↑](#footnote-ref-16)
17. *The supply, manufacture, importation and distribution of unlicensed cannabis-based products for medicinal use in humans ‘specials’* (MHRA, 2018). [↑](#footnote-ref-17)
18. Importing an unlicensed medicinal cannabis product without a Home Office licence is a criminal offence: Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015 (2015 Order). [↑](#footnote-ref-18)
19. K. O’Brien, ‘Medicinal Cannabis: Issues of Evidence.’ (2019) 28 *European Journal of Integrative Medicine* 114. [↑](#footnote-ref-19)
20. S.232 Health and Social Care Act 2012. [↑](#footnote-ref-20)
21. ‘CBMPs’ for the purposes of the NICE Guideline are more broadly defined than CMPs in the 2018 regulations, as they include pure cannabidiol, licensed products (i.e. currently, Sativex, Epidiolex and nabilone) and synthetic cannabinoids. [↑](#footnote-ref-21)
22. *Cannabis Based Medicinal Products*, NG144 (published November 2019). [↑](#footnote-ref-22)
23. NG144, 1.3. [↑](#footnote-ref-23)
24. This appraisal informed the anticipated Technology Appraisal Guideline published in December 2019: <https://www.nice.org.uk/guidance/indevelopment/gid-ta10410/documents>. [↑](#footnote-ref-24)
25. *Making Decisions Using NICE Guidelines* (accessible at <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/making-decisions-using-nice-guidelines>). [↑](#footnote-ref-25)
26. NG-144, 1.2.1 [↑](#footnote-ref-26)
27. NG144, 1.2.2. [↑](#footnote-ref-27)
28. E.g. See *Guidance for the use of medicinal cannabis in the treatment of chronic non-cancer pain in Australia* (Australian Government, Department of Health, Therapeutic Goods Administration,2017). [↑](#footnote-ref-28)
29. ‘Rationale and Impact’ in NG-144. [↑](#footnote-ref-29)
30. Cannabis-based medicinal products: Draft for Consultation (NICE, August 2019): with a narrow two month window for consultation responses. [↑](#footnote-ref-30)
31. It is unusual but not unknown for NICE to recommend an unlicensed product: *Luc Jones v Taunton & Somerset NHS Foundation Trust* [2019] EWHC 1408. [↑](#footnote-ref-31)
32. J. Miola, ‘Innovation in Medicine through degeneration in law?: A critical perspective on the Medical Innovation Bill,’ (2014) 14(4) MLI 266 at 268. [↑](#footnote-ref-32)
33. For a definition of off label prescribing see *Glaxo Wellcome UK v Sandoz Ltd* [2019] EWHC 2545 at 40: prescribers can, in the exercise of their own clinical judgment and at their own risk, prescribe an authorised drug for an unauthorised indication and/or for an unauthorised patient group. [↑](#footnote-ref-33)
34. See *Guidance for the use of medicinal cannabis in the treatment of chronic non-cancer pain in Australia* (Australian Government, Department of Health, Therapeutic Goods Administration,2017) reviewing randomised studies of medicinal cannabis and reporting ‘moderate confidence’ that nabiximols (e.g. Sativex) can produce 50% and 30% reported reductions in chronic non cancer pain (at 1.1). [↑](#footnote-ref-34)
35. Research suggests a variable response between physicians to priority setting mechanisms: M. Kimmel, ‘Challenges in regulating priority setting in healthcare: a Finnish perspective on a law maker’s dilemma.’ (2019) 19(2) MLI 136. [↑](#footnote-ref-35)
36. S. Devaney and S. Holm, ‘The Transmutation of Deference in Medicine: An Ethico-Legal Perspective.’ (2018) 26(2) Med L Rev 202. [↑](#footnote-ref-36)
37. ‘Rationale and Impact’ in NG-144. [↑](#footnote-ref-37)
38. E.g. *Guidance on the use of cannabis‐based products for medicinal use in children and young people with epilepsy* (BPNA, 2018) at 4.1. [↑](#footnote-ref-38)
39. A Samanta et al, ‘The Role of Clinical Guidelines in Medical Negligence Litigation: A Shift from the *Bolam* Standard?’ (2006) 14 Med L Rev 321 finding that lawyers used NICE guidelines as a trial strategy. [↑](#footnote-ref-39)
40. # Breaching the guidance can result in fitness to practise proceedings, e.g. *Finegan v GMC* [1987] 1 WLR 121 - fitness to practise found wanting for breach of prescribing rules by prescribing anti-depressants for wife following bereavement when she had lost faith in her own doctor (this would be a potential breach of para 17 of the current guidance).

    [↑](#footnote-ref-40)
41. This much seems well established in case law, e.g. *R v Secretary of State for Health, ex p Pfizer Ltd.* (1999) 51 BMLR 189, 198 – although referring to a Secretary of State letter appearing to encroach on clinical judgement, rather than NICE guidelines. See also House of Commons Select Committee, *Drugs Policy: Medicinal Cannabis* published July 2019 – ‘the interim guidance, as well as forthcoming guidance created by NICE, is advice and not an instruction to prevent prescribing,’ at 75. <https://publications.parliament.uk/pa/cm201719/cmselect/cmhealth/1821/182107.htm>.  [↑](#footnote-ref-41)
42. NG-144, p2. [↑](#footnote-ref-42)
43. [2015] EWHC 2301 at [52] which met with agreement from the Court of Appeal ([2017] EWCA Civ 151 ([34-38]). The reframing of the issue in the Supreme Court meant that the NICE guidance was not discussed. [↑](#footnote-ref-43)
44. [2019] EWHC 938. A similar outcome can be observed in *Corke v Princess Alexandra NHS Trust* [2019] EWHC 487. [↑](#footnote-ref-44)
45. Ibid at [22]. [↑](#footnote-ref-45)
46. *Montgomery v Lanarkshire Health Board* [2015] UKSC 11. [↑](#footnote-ref-46)
47. *R (Rose) v Thanet Clinical Commissioning Group* [2014] EWHC 1182 – where a Clinical Commissioning Group had departed from guidelines. [↑](#footnote-ref-47)
48. [2019] EWHC 938 at [30]. [↑](#footnote-ref-48)
49. See *Interim policy on cannabis-based medicinal products* (Care Quality Commission, 2019), KLOE E1. [↑](#footnote-ref-49)
50. E.g. NHS England, *Letter: Guidance to Clinicians on Cannabis Based Products for Medicinal Use* (2018) referring to discussing with a peer clinician in the same specialism as good practice. [↑](#footnote-ref-50)
51. Regulation 4 of the *Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (E.W.&S) Regulations 2018* (SI 2018 No.1055) – the medicinal product must be ‘for use in accordance with a prescription or direction of a specialist medical practitioner’ and NG-144 at 1.5. [↑](#footnote-ref-51)
52. See G. Greenfield, ‘Rethinking primary care’s gatekeeper role’ (2016) 354 BMJ 4803. Even the new medicinal cannabis clinics prefer to start from a GP referral: <https://themedicalcannabisclinics.com/faqs/> - ‘Do I need a letter of referral?’ [↑](#footnote-ref-52)
53. K. Gardiner et al, ‘Health professional beliefs, knowledge and concerns surrounding medicinal cannabis – a systematic review.’ (2019) 14(5) PLOS ONE e0216556. [↑](#footnote-ref-53)
54. See BPNA, n.38 at 5.1 and *Cannabis Based Medicines: an Interim Desktop Guide* (Royal College of General Practitioners, 2018) at 1.0: ‘The product must be supplied by a specialist doctor and there are no shared care arrangements. GPs should not prescribe these products…’ [↑](#footnote-ref-54)
55. Regulation 4 of the *Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (E.W.&S) Regulations 2018* (SI 2018 No.1055) (emphasis added). [↑](#footnote-ref-55)
56. NG 144, at 1.5.2. [↑](#footnote-ref-56)
57. ibid. [↑](#footnote-ref-57)
58. Hannah Deacon recounts how her son’s first neurologist threatened to report her to social services if she gave cannabis oil to her son: ‘The medical cannabis campaign is not yet over.’ *Hospital Times.* April 2019. See also K. Gardiner et al, ‘Health professional beliefs, knowledge and concerns surrounding medicinal cannabis – a systematic review.’ (2019) 14(5) PLOS ONE e0216556 finding that studies commonly reported common fears that patients were seeking a prescription as a façade for recreational use. [↑](#footnote-ref-58)
59. E.g. use of a product licenced for that condition should be considered first, then ‘off label’ prescribing, before considering an unlicensed CMP as a ‘third line’ option: <https://www.england.nhs.uk/medicines/support-for-prescribers/cannabis-based-products-for-medicinal-use/cannabis-based-products-for-medicinal-use-frequently-asked-questions/#will-these-products-be-prescribed-as-first-line-treatments>. [↑](#footnote-ref-59)
60. *Montgomery v Lanarkshire Health Board* [2015] UKSC 11. [↑](#footnote-ref-60)
61. M. Bone and T. Seddon, ‘Human rights, public health and medicinal cannabis use’ (2016) 26(1) *Critical Public Health* 51, see also O’Brien (n.19). [↑](#footnote-ref-61)
62. <https://www.nhs.uk/conditions/medical-cannabis/> - (emphasis added) last updated Nov 2018. [↑](#footnote-ref-62)
63. [2015] UKSC 11 at [81]. [↑](#footnote-ref-63)
64. T. Cockburn & M. Fay, ‘Consent to Innovative Treatment’ (2019) 11 (1) *Law Innovation and Technology* 34 at 46. [↑](#footnote-ref-64)
65. *Good practice in prescribing and managing medicines and devices* (GMC, 2013). [↑](#footnote-ref-65)
66. ibid, para 14. [↑](#footnote-ref-66)
67. ibid, para 68. [↑](#footnote-ref-67)
68. ibid, para 70. [↑](#footnote-ref-68)
69. W. Notcutt et al, ‘Initial experiences with medicinal extracts of cannabis for chronic pain: Results from 34 ‘N of 1’ studies’ (2004) 59 *Anaesthesia* 440. [↑](#footnote-ref-69)
70. NG-144 at 1.5.5. [↑](#footnote-ref-70)
71. E.g., Australia (O’Brien, ibid, (n.19), Ireland (N. Nelligan, ‘Medicinal cannabis and the law in Ireland - a critical evaluation of doctor-patient access to medicinal cannabis under the existing licensing rules and the Government's proposed enhanced access scheme’(2018) 24(2) MLJI 106). [↑](#footnote-ref-71)
72. Se e.g. Evidence recently gathered by New Zealand’s Ministry of Health usefully summarised in M. Rychert et al, ‘Medicinal Cannabis Scheme in New Zealand’ (2019) 1503 NZMA 8. [↑](#footnote-ref-72)