

## UK: NICE consults on draft guideline on prescribing medicinal cannabis

On 8 August 2019, the National Institute for Health and Care Excellence (**NICE**)<sup>1</sup> published a draft guideline on prescribing cannabis-based medicinal products (the **Draft Guideline**) for consultation<sup>2</sup>. The Draft Guideline, which, when finalised, will replace interim clinical guidance issued by specialist medical societies, makes recommendations regarding prescribing cannabis-based medicines for people with intractable nausea and vomiting, chronic pain, spasticity, and severe treatment-resistant epilepsy. The Draft Guideline's scope extends to both licensed and unlicensed cannabis-based medicinal products, including "cannabis-based products for medicinal use" (**CBPMs**). As outlined in our June article, CBPMs were rescheduled as Schedule 2 drugs under the Misuse of Drugs Regulations 2001<sup>3</sup> in November 2018, in theory making them more accessible under the UK's "Specials" medicines framework.<sup>4</sup>

However, recent reports indicate that there have been only a handful of NHS prescriptions for CBPMs since their rescheduling.<sup>5</sup> Various sources, including the House of Commons Health and Social Care Committee's report on medicinal cannabis<sup>6</sup> and NHS England's review of barriers to accessing CBPMs,<sup>7</sup> indicate that those specialist clinicians able to prescribe CBPMs are, for the most part, unwilling to do so in the absence of better evidence on their long-term safety and effectiveness and clear clinical guidance specifying that such products may be appropriate in certain circumstances. However, the Draft Guideline takes a restrictive approach to prescribing CBPMs and other cannabis-based medicinal products, with some suggesting that it diminishes even further the prospect of doctors obtaining approval from their NHS trust to prescribe such products.<sup>8</sup>

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<sup>1</sup> NICE's role is to seek to improve outcomes for people using the NHS and other public health and social care services. In doing this, NICE produces, *inter alia*, guidance on prescribing medical products for a range of medical conditions.

<sup>2</sup> NICE: Guideline: Cannabis-based medicinal products: Draft for consultation (August 2019) <https://www.nice.org.uk/guidance/GID-NG10124/documents/draft-guideline>

<sup>3</sup> The Misuse of Drugs Regulations 2001 (SI 2001/3998). CBPMs were similarly rescheduled under the Misuse of Drugs Regulations 2002 (Northern Ireland) 2002 (SR 2002/1).

<sup>4</sup> Allen & Overy: The cannabis market: helping investors navigate the UK regulatory regime (June 2019) <http://www.allenoverly.com/SiteCollectionDocuments/The-cannabis-market-helping-investors-navigate-the-UK-regulatory-regime.pdf>

<sup>5</sup> NHS England and NHS Improvement: Barriers to accessing cannabis-based products for medicinal use on NHS prescription: Findings and recommendations (8 August 2019) <https://www.england.nhs.uk/wp-content/uploads/2019/08/barriers-accessing-cannabis-based-products-nhs-prescription.pdf>

<sup>6</sup> House of Commons Health and Social Care Committee: Drugs policy: medicinal cannabis, Sixteenth Report of Session 2017-19 (3 July 2019) <https://publications.parliament.uk/pa/cm201719/cmselect/cmhealth/1821/1821.pdf>

<sup>7</sup> Above n 5.

<sup>8</sup> The Pharmaceutical Journal: NICE guidance on medical cannabis products criticised as 'restrictive and negative' (8 August 2019) <https://www.pharmaceutical-journal.com/news-and-analysis/news/nice-guidance-on-medical-cannabis-products-criticised-as-restrictive-and-negative/20206930.article>

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# The draft guideline: key recommendations

With the exception of nabilone (a synthetic cannabinoid with a marketing authorisation) for adults with intractable nausea and vomiting, the Draft Guideline does not recommend any cannabis-based medicinal products, including CBPMs, for patients with intractable nausea and vomiting, chronic pain, spasticity, or severe treatment-resistant epilepsy. Instead, the Draft Guideline makes recommendations for priority research into the clinical (and cost) effectiveness of:

- cannabis-based medicinal products for (i) spasticity and (ii) intractable pain in children and young people, as an add-on treatment;
- cannabidiol (**CBD**) in combination with delta-9-tetrahydrocannabinol (**THC**)<sup>9</sup> for epileptic disorders; and
- CBD for (i) epileptic disorders and (ii) fibromyalgia or persistent treatment-resistant neuropathic pain in adults, as an add-on treatment.

NHS England, in its report on barriers to accessing CBPMs,<sup>10</sup> recommends that the National Institute for Health Research (**NIHR**) supports research into the priority areas recommended by NICE in the Draft Guideline. The NIHR's most recent call for proposals on CBPMs closed on 31 July 2019.

Despite the above, the Draft Guideline does make recommendations concerning who can prescribe cannabis-based medicinal products that might make it easier to access these products where they are determined to be appropriate in a given case. In particular, the Draft Guideline provides that, whilst initial prescriptions of these products must be made by a specialist doctor, subsequent prescriptions may be issued by another prescriber as part of a "shared care" arrangement. Such a shared care arrangement is the subject of a current case before the High Court in Belfast.<sup>11</sup> In that case, the applicant is seeking judicial review of the decision of Northern Ireland health officials to block a shared care arrangement under which a local general practitioner agreed to prescribe CBPMs with the support of a specialist doctor based in London.

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<sup>9</sup> CBD and THC are the two main cannabinoids (of which there are over 100) in cannabis, with THC being the main psychoactive component.  
<sup>10</sup> NHS England and NHS Improvement: Barriers to accessing cannabis-based products for medicinal use on NHS prescription: Findings and recommendations, published (8 August 2019) <https://www.england.nhs.uk/wp-content/uploads/2019/08/barriers-accessing-cannabis-based-products-nhs-prescription.pdf>.

<sup>11</sup> This case was brought by Charlotte Caldwell, the mother of Billy Caldwell, one of the children whose severe epilepsy prompted the November 2018 rescheduling of CBPMs. See further Health Europa: Discover how Charlotte Caldwell is challenging the medical cannabis law (24 June 2019) <https://www.healtheuropa.eu/caldwell-medical-cannabis-law/92117/>

## Next steps

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The consultation period for the Draft Guideline runs until 5 September 2019. The NICE committee will then consider and respond to stakeholder comments, and make any necessary revisions to the Draft Guideline. The final Guideline is expected to be published in early November 2019.

If you have any questions or would like assistance with preparing comments on the Draft Guideline, please contact the authors Matt Townsend and Isabella Kelly or other key contacts in our Cannabis practice.

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