

ACMD: Cannabis-Based Products for Medicinal Use – Call for Evidence.

Section 1: About Yourself / Your Organisation

Q1. Tell us about the capacity in which you are replying.

This submission should be considered representative of the Cannabis Trades Association (CTA), which represents businesses across the UK hemp and Cannabis sector. The response reflects the collective expertise and observations of CTA members engaged in cultivation, manufacturing, clinical services, import and export, compliance, research, and patient advocacy related to cannabis-based products for medicinal use (CBPMs).

Q2. Please tell us which category best applies to you:

Industry (manufacturer, importer, educator, and compliance stakeholder).

Q3. Please describe your personal expertise within this area and/or the nature of your organisation and your role.

The Cannabis Trades Association is the UK's longest-standing trade body for the cannabis and hemp industries, representing members involved in the lawful cultivation, manufacture, distribution, and prescription support of cannabis and hemp-derived products. The CTA liaises with regulatory authorities including the Home Office, MHRA, FSA, DEFRA, and DHSC. Through its members, the CTA has direct insight into barriers, compliance systems, and patient outcomes relating to CBPMs, and contributes evidence-based recommendations to support safe, lawful, and patient-centred access.

Q4. Please select the setting in which you work.

Not applicable (industry and regulatory association, not a clinical practice).

Q5. Do you prescribe CBPMs as part of your role?

No. However, the CTA represents multiple clinics, prescribers, wholesale distribution agents, laboratories, and

growers/producers/manufacturers operating under Schedule 2 licensing who prescribe or supply CBPMs within regulatory frameworks.

Q6. What type of service do you provide?

The CTA provides membership, regulatory guidance, training, advocacy and policy representation. It promotes compliance and engagement between government departments and the lawful cannabis and hemp industries to improve public health outcomes, professional standards, and legislative alignment.

Section 2: Clinical Practice

Q7. What are the barriers to prescribing CBPMs through the NHS?

The key barriers include:

- **Restrictive prescribing criteria:** Only specialist doctors listed on the GMC register may prescribe CBPMs, which excludes most GPs and limits access and scalability.
- **Institutional caution:** NHS Trusts often impose internal prescribing policies that discourage CBPM prescriptions due to perceived reputational risk, lack of NICE endorsement, or uncertainty over liability.
- **The ACMD are treating a plant-based medicine** as though it were a synthetic medicine produced using double blind trials and applying the same cautionary principle to it.
- **Insufficient clinical data integration:** The current lack of centralised real-world evidence/data collection from private clinics means NHS decision-making is driven by limited datasets.
- **Cost and procurement:** CBPMs are not yet embedded in NHS procurement systems, leading to funding and supply challenges.
- **Professional training gaps:** Many clinicians lack education on the endocannabinoid system and cannabinoid pharmacology.

Q8. How can access to CBPMs through the NHS be improved?

- Broaden prescribing authority to include **experienced independent prescribers and GP specialists**.
- Develop **national clinical guidance** that incorporates international real-world data, including evidence from Germany, Canada, Australia, and Israel.
- Establish a **central Cannabis Office** to coordinate licensing, data collection, and clinician support.
- Introduce **public-private research partnerships** to accelerate understanding and reduce stigma.

- Ensure **clear reimbursement frameworks** so NHS Trusts can prescribe without financial disincentive.

Q9. How are patient outcomes for CBPMs currently evidenced and registered in the NHS and/or private clinics?

Patient outcomes in the private sector are primarily captured via patient-reported outcome measures (PROMs), clinic audits, and anonymised case series, rather than standardised NHS datasets.

NHS prescribing remains extremely limited; where it occurs, outcomes are logged through existing systems such as the Clinical Practice Research Datalink (CPRD). The lack of national alignment prevents meaningful analysis of efficacy, dosage, or long-term benefit.

Private clinics are reticent to advise patients to use the MHRA Yellow Card Scheme or indeed make notifications themselves, for commercial reasons.

Q10. How do specialist doctors in the NHS and/or private clinics that prescribe CBPMs communicate with the patient's GP and other services involved in their care?

Communication varies between providers.

In well-regulated clinics, discharge summaries and ongoing communication letters are routinely sent to GPs. However, there is **no standardised national communication protocol**, leading to fragmented care.

For example, Shared Care: The Prescribing Consultant may have a shared care duty with the patient's GP, however these prescriptions are still paid privately, despite being signed off by a GP. If the doctor is an NHS doctor these prescriptions should logically then be treated as NHS prescriptions.

Tele-medicines and one-to-one consultations, in-person or online, are excellent and should be continued.

The CTA supports the introduction of mandatory electronic reporting between prescribers, pharmacies, and GPs through NHS Digital to ensure continuity of care.

Q11. To what extent are you aware of the positive and negative effects of CBPMs?

The CTA and its members maintain a comprehensive understanding based on published literature and member experience.

Positive effects include improved quality of life in conditions such as chronic pain, anxiety, spasticity in MS, and treatment-resistant epilepsy.

Negative effects are typically mild and transient, such as dry mouth, dizziness, or fatigue, though monitoring for cognitive impairment or other side effects and contraindications is appropriate.

The overall risk profile is substantially lower than many controlled pharmaceuticals currently prescribed for similar indications.

We understand that some people are taking high THC CBPMs which are not necessarily needed for any particular treatment. We realise that some people may be more resistant to THC and that individual clinical needs vary.

Q12. What is the impact of non-medical prescribers prescribing CBPMs?

Non-medical prescribers are currently limited by law from independently prescribing CBPMs. However, extending prescribing authority under thorough training, supervision and monitoring could **greatly enhance accessibility and continuity of care**, particularly in primary and community settings. This would also alleviate specialist bottlenecks while maintaining patient safety.

Letters of Need requested by Prescribing Clinicians ordering CBPMs are also creating yet another bottleneck within the supply chain.

Q13. Are there cases where Sativex, Epidyolex, and Nabilone have been prescribed outside the terms of the licence (off-label) in the NHS and/or private clinics?

There are known instances of off-label prescribing within both NHS and private contexts where clinical judgment supports patient benefit - particularly in palliative care or refractory conditions. Such prescribing is consistent with wider medical practice and should be legitimised under strengthened clinical governance rather than penalised. The supply needs to be widened to include orphan medication such as, but not exclusively to: Bedrocan, Bedrolite, Bedica, Bedrobinol, and Bediol.

Q14. What conditions do you think it is appropriate to consider use of CBPMs for?

CBPMs are appropriate for conditions where conventional treatments have proven ineffective or intolerable, including but not limited to:

- chronic neuropathic pain,
- spasticity in MS,
- epilepsy,
- PTSD,
- anxiety,
- sleep disorders, and
- cancer-related pain or nausea.

Evidence and international experience suggest further therapeutic potential in inflammatory, neurodegenerative, and psychiatric conditions.

Section 3: Patient Experience

Q15. What are the barriers to accessing CBPMs through the NHS?

- Very few NHS prescribers authorised or willing to prescribe due to lack of knowledge and support.
- Lack of clear referral pathways and local commissioning frameworks.
- Stigma and misinformation among healthcare professionals.
- Limited product availability through NHS supply chains.
- Absence of consistent data supporting NHS formulary inclusion.

Q16. What are the main issues faced by patients from the NHS and/or private clinics?

Patients frequently face:

- High costs in the private sector due to import and licensing expenses.
- Disruption to the supply chain causing the patient to accept replaced similar CBPMs with consequences to the patients' treatments.
- Difficulty transferring from private to NHS care even under Shared Care protocols.
- Fragmented care and lack of GP engagement.
- Travel barriers and costs of using private specialist clinics, causing societal inequality.
- Uncertainty about legality and disclosure, leading to anxiety and stigma for CBPM patients.
- Hospitals REFUSE to allow the patients to administer their own medication in a safe environment and will not administer it on behalf of the patient, in many cases.
- Hospices and clinics offering palliative care should be trained in the use of CPBMs to avoid overuse of opioids and 'end-of-life' medicines rendering the patient unconscious.

Q17. Do patients in the NHS and/or private clinics continue to use other prescribed licensed cannabis-based medicines alongside CBPMs?

Yes, particularly in cases involving polypharmacy for chronic pain or neurological conditions. Some patients transition from conventional cannabinoids (e.g. Nabilone) to full-spectrum CBPMs. Better clinical oversight is required to ensure safety and avoid duplication.

Q18. How can the patient experience regarding CBPMs be improved in the NHS and/or private clinics?

- Introduce **clear, consistent care pathways** integrating both NHS and private providers.

- Provide **training for GPs and specialist prescribers** to support patients already prescribed CBPMs.
- Establish a **national patient registry** for monitoring outcomes and side effects.
- Reduce **cost barriers** through NHS coverage, UK supply of CBPMs, and importation reform.
- Ensure **public and workplace education campaigns** to combat stigma and outdated preconceptions.
- Access to a **wide range of formats and dosages** such as: choice of flower for vaporising, tinctures, topicals, dermal patches, suppositories, pessaries etc.

Section 4: Legislation, Licensing and Regulation

Q19. What are the key challenges with the current legislation for CBPMs licensing and regulation?

- CBPMs remain Schedule 2 controlled substances, creating disproportionate administrative burdens and costs.
- The Misuse of Drugs Regulations (2018) failed to provide a clear operational framework for cultivation, processing, and prescription.
- The **Home Office licensing process is opaque**, costly, and inconsistent, discouraging domestic production. The department also is overwhelmed with firearms licensing! The HO Firearms and Drugs Licensing Unit is currently suspending new licensing due to being under-resourced.
- Lack of **inter-departmental coordination** between the Home Office, MHRA, and DHSC obstructs innovation and research.

Q20. Please describe the impact of the rescheduling of CBPMs in 2018 and any unintended consequences.

While the 2018 rescheduling theoretically allowed specialist prescribing, in practice it created a **two-tier system**: limited NHS access versus an expensive private sector.

The policy's intent, to support compassionate access, has been undermined by lack of implementation mechanisms. Unintended consequences include increased reliance on private clinics, inequity of access, and the growth of informal or unregulated use by patients unable to afford prescriptions. Patients who cannot afford are self-medicating without thought of safety of the products being consumed and their full traceability (heavy metals, pesticides, mould, and synthetic drug additions).

Section 5: Research

Q21. What are the barriers to researching CBPMs?

- **Controlled drug scheduling restrictions** complicated research approvals.
- **Licensing delays** and cost-prohibitive Home Office processes.
- **Limited domestic cultivation, manufacture and handling licences**, forcing reliance on imported materials and lack of Wholesale Distribution Agent choices.
- **Insufficient public funding** compared with potential positive public health impacts.
- **Ethical and data governance confusion** regarding real-world evidence from private clinics who are reticent to share data, even anonymised datasets.

Q22. How can barriers to research on CBPMs be addressed?

- Establish a **single-point Cannabis Office** coordinating licensing and data access.
- Allow **Schedule 2 exemptions** for accredited research institutions and medical cannabis licensees.
- Facilitate **public-private partnerships** with data-sharing agreements.
- Adopt **international alignment** to support mutual recognition of peer reviewed studies.
- Establishing teaching hospital hubs to **treat complex conditions with CBPMs** to establish Real World Data for efficacy of treatment.
- Amend the **Proceeds of Crime Act 2002** to exclude regulated and licensed operators of CBPMs. This will encourage investment, research and development outcomes, putting the UK at the head of plant based medicine research.

Q23. Please tell us about any ongoing research or published evidence relating to CBPMs that you are aware of.

The CTA is aware of multiple ongoing studies and databases including Project Twenty21, Drug Science observational studies, and clinical data emerging from Canadian, Australian, Israeli and German programs. We are aware of a UK based company that is preparing to trial CBPMs on Endometriosis, and for PTSD and anxiety related conditions.

Collectively, these datasets demonstrate positive outcomes in pain, anxiety, PTSD, and sleep disorders. There is strong international consensus supporting expanded access within a regulated framework.

Section 6: Awareness and Education

Q24. Please describe the level of public awareness for legislative and regulatory changes regarding CBPMs.

Public awareness remains **moderate but confused**.

Many people mistakenly believe CBPMs are fully legal and widely available through the NHS, while others are unaware that private prescriptions are lawful. Misinformation from media and **outdated NHS web guidance** contributes to patient reluctance and GP resistance.

A coordinated government-led communications strategy is required, aligned with professional medical bodies, to clarify lawful use and routes to access.

Q25. Please describe the level of professional awareness and education among healthcare professionals regarding CBPMs, and how it can be improved.

Professional awareness of CBPMs among UK clinicians remains inconsistent and, in many settings, limited. While a small cohort of specialists and private clinicians have developed practical expertise, most prescribers—particularly in primary care—report gaps in knowledge of the endocannabinoid system, product types and formulations, pharmacology (including pharmacokinetics and pharmacodynamics), dosing and titration, drug–drug interactions (e.g., with CNS depressants and antiepileptics), contraindications, and monitoring/recording requirements for controlled drugs. Pharmacists and multidisciplinary teams also report uncertainty about product equivalence, switching, and continuity of supply, which contributes to reluctance to support existing prescriptions.

These deficits are compounded by the absence of a standardised national curriculum, variable local governance policies, and limited access to accredited continuing professional development. As a result, clinical decisions are often shaped by institutional caution rather than evidence, and communication between specialists, GPs, and pharmacies is uneven—undermining shared care and continuity for patients.

Improvements the CTA recommends:

- **National competency framework:** Develop an NHSE-endorsed competency and capability framework for CBPMs that covers clinical assessment, initiation and titration, adverse event recognition, deprescribing/switching, safeguarding, and governance for Schedule 2 medicines.
- **Accredited CPD and e-learning:** Commission accredited modular training (foundation, intermediate, advanced) for doctors, pharmacists, and nurses, with assessment and certification linked to clinical privileges for CBPM prescribing/support.

- **Undergraduate curricula:** Introduce core teaching on the endocannabinoid system and CBPM pharmacology within medical, pharmacy, and nursing degrees.
- **Clinical tools and guidance:** Provide national dosing guides, product equivalence charts, formulary-style monographs, and switching protocols to support safe substitution during supply disruptions.
- **Standardised communication:** Implement mandatory electronic information sharing between specialist prescribers, community pharmacies, and GPs (e.g., structured clinic letters, shared care agreements, and PROMs integration).
- **Pharmacy readiness:** Fund targeted training for community and hospital pharmacists on verification, storage, dispensing, counselling points, and incident reporting pathways.
- **Safety reporting culture:** Embed routine use of established pharmacovigilance channels and local incident reporting, with clear feedback loops to clinicians.
- **Leadership & hubs:** Establish regional teaching-hospital hubs to mentor clinicians, host case conferences, and consolidate real-world data to inform best practice and guideline development.

Raising professional literacy in these areas will reduce unwarranted variation, support safe and equitable access, and give clinicians the confidence to manage CBPMs within mainstream care.

Section 7: Illicit and Non-Medical Use

Q26. Did the rescheduling of CBPMs in 2018 impact illegal cannabis use? Please describe.

The rescheduling had **minimal measurable impact** on illicit cannabis use. Because NHS access remains limited, most individuals continue to rely on unregulated supply channels to manage medical needs.

Many legacy self-medicating cannabis users are now turning to private prescriptions to avoid legal enforcement implications for their work, travel, and day-to-day life.

There is little to no new uptake in the youth.

Evidence from other jurisdictions shows that expanding lawful access significantly reduces illicit market dependence, health issues from illicit use and supply, improves safety, and supports law enforcement by distinguishing legitimate medical use.

There is good supporting data that the medical costs of widescale illicit use, is still cheaper and better than the costs, harms, and outcomes from current prescribed medications such as opioids, opiates, benzodiazepines and other illegal highly addictive drugs (DMT, GHB, Cocaine, Heroin, Fentanyl and amphetamines).

Section 8: Any Further Comments

The Cannabis Trades Association urges the Home Office and relevant departments to recognise the substantial evidence base and international precedents supporting medical cannabis reform. The CTA recommends:

1. Creation of a **Cannabis Office** to coordinate regulation, licensing, and research.
2. **Alignment of UK frameworks** with international medical cannabis standards to unlock domestic cultivation and manufacturing.
3. **Inclusion of CBPM data** within NHS England's Digital Health infrastructure.
4. Improved public education and professional training.
5. **Recognition of patient equality** by ensuring NHS access aligns with the right to evidence-based treatment.
6. Amend the **Proceeds of Crime Act 2002** to exclude regulated and licensed operators of CBPMs.
7. The ACMD need to review their protocol on Plant Based Medicines regarding **risk verses benefit** criteria.