JUSTICE by DESIGN

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10/11/2025

Discrimination by Design

The legal flaws of Regulation 16A3 of the Misuse of Drugs Regulations 2011 (as amended in 2018)

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Foreword: Diagnosing a Systemic Condition

Without reference to any particular long-term treatment or condition, the links between health and the policy outcomes intended by Parliament in enabling the 2018 legislative changes almost force a comparison of the policy model itself to a chronically ill patient.

In November 2018, cannabis-based products were rescheduled to permit prescription under specialist supervision — a reform designed to restore clinical autonomy and relieve suffering for those with chronic and intractable conditions.

Discrimination by Design examines what happens when a framework intended to heal instead embeds harm. The analysis and accompanying Annexes A–E can be seen as various diagnostic procedures — each one a test, a scan, or a specialist opinion revealing deeper dysfunction within the regulatory body. The Freedom of Information requests (Annex F) act as investigative imaging — tracing origins, confirming whether proper assessments were ever undertaken, and identifying where oversight failed.

This process exposes what can be described as a policy trap — a feedback loop in which measures designed to mitigate risk instead reinforce some of the barriers they were meant to remove. The controls intended to ensure safety and compliance have instead entrenched inequity, preventing the system from returning to health.

What emerges is a picture of systemic pathology: a regulatory condition misdiagnosed at birth and left untreated. The treatment plan — the 2018 framework — addressed symptoms but not causes, leaving the system chronically unstable and patients at risk.

The purpose of this work is not simply to record harm but to help guide recovery. The same principles that define effective medicine — listening to patients, interrogating evidence, addressing causes rather than symptoms, and continuously reviewing outcomes — must guide reform if the health of the system is to be restored. The analysis that follows applies that same diagnostic discipline to policy itself: evidence, causation, and outcomes.

I hope that this analysis can serve as a small but useful paving stone toward rebuilding insight, empathy, and legitimacy between patients and those responsible for their care and regulation. As Government considers the future of the legal framework governing cannabis-based products for medicinal use, the opportunity exists for genuine collaboration between patients, clinicians, regulators, and enforcement authorities — one grounded in openness, shared understanding, and respect for patient-centred, evidence-based care.

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Change Log

Document: Discrimination by Design: The legal flaws of Regulation 16A3
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Summary of Revisions

Date	Version / Section	Change Description	Reason / Context	Author / Editor
18 Sept 2025	V1.0	Initial version shared with Ministers	Original version lacked change log and contained personal contact details.	PL
Oct/ Nov 2025	V2.0 – Entire doc	**Correction: References to *SI 2018 No. 1056* in relation to the rescheduling of cannabis-based medicinal products should read *SI 2018 No. 1356 – The Misuse of Drugs Act 1971 (Amendment) (No. 2) Order 2018*.** This was1356 the affirmative Order debated and approved by Parliament. *SI 2018 No. 1055* (negative) remains correctly cited as the instrument that inserted Regulation 16A(3) and the prohibition on smoking. Added NEW foreword Added change log and repaginated. Justicebydesign logo and contact details updated Reinstated Annex C from initial correspondence dated 16 June 2025 Added Supplementary Annexes D&E alongside main analysis "Discrimination by Design" Cross referenced and updated core document to reflect inaccuracies identified via detailed analysis at Annex D Inserted NEW Annex F – FOI requests to Home Office and Department for Health and Social Care.	Consistency with cross-govt correspondence and alignment of all evidence with detail set out in relevant annexes.	PL

Key Changes Since Last Version

Inserted Annex G for completeness – Initial correspondence with Government – June 2025

V2 Chronology

18/09/25 Content as submitted to Government Departments, Met Police, NHS and Mayor of London as "Discrimination by Design and Annexes A-C"

16/10/25 Open Letter, "Discrimination by Design", "Supplementary Annexes D&E" submitted to ACMD call for Evidence

17/10/25 Supplementary Annexes D&E shared with Government Departments, Met Police, NHS and Mayor of London.

10/11/25 V2. Consolidated version of "Discrimination by Design" issued to Government Departments, incl. Annexes A-E. No changes have been made to Analytical content;

V2 contains the following insertions not previously shared with Government or ACMD.

- Explanatory links related to Annex D (highlighted yellow)
- Foreword & Change Log
- New Annex F – FOI's issued to Home Office and Department for Health and Social Care.

1. Executive Summary

1.1. Overview

This briefing examines the lawfulness of **Regulation 16A(3)** of the Misuse of Drugs Regulations 2001. That provision excludes **smoking** from the lawful definition of cannabis-based products for medicinal use in humans (CBPMs), even when **lawfully prescribed** by a specialist. The result is unique in UK medicines law: **the same medicine is lawful in one form and criminal in another**. For patients who require the fastest onset, the choice is **therapeutic failure or criminality**.

1.2 Key findings

1. **Discrimination by design.** A route ban excludes disabled patients who need rapid onset. The Equality Act 2010 and Article 14 ECHR are engaged. See Section 8.
2. **Policy without evidence.** No consultation preceded the ban, no published Equality Impact Assessment was undertaken, and only a brief de minimis Impact Assessment of unclear status exists which omitted equality and clinical analysis. No statutory review has been conducted since 2018; neither **NICE** nor **MHRA** recommended a smoking prohibition. See Section 11 & Annex D. ***Editorial update highlighted to broaden explanation***
3. **Circular policy trap.** Evidence is demanded while prescribing is withheld; patients are locked out of both access and evidence. See Section 7.
4. **Policy contradictions.** Tobacco and alcohol (no medical benefit) are permitted; high-risk medicines (opioids, benzodiazepines, ketamine) are permitted **without** route bans; only cannabis smoking is prohibited. See Section 13.
5. **Comparative/international context.** Peer jurisdictions regulate rather than prohibit medical smoking when clinically indicated. See Section 14.

1.3 Legal vulnerabilities

- **Equality Act 2010:** route-based barrier (ss.20–21, s.29).
- **HRA 1998:** disproportionate Article 8 interference, compounded by Article 14 discrimination.
- **Procedural illegality:** no consultation, no review, no equality assessment.
- **Purpose frustration:** secondary legislation undermines Parliament's 2018 intent to enable clinical access.

1.4 Real-world consequences

Patients are criminalised for the only route that can act **within seconds, often from the first puff**, moderating or halting symptoms as they emerge. For many, this immediacy is the difference between preventing escalation and hospitalisation. Prescriptions are withdrawn if smoking is disclosed; employers discipline or dismiss; police, courts and the NHS waste resources; disabled people bear the greatest harm. See **Section 12**.

Patient's Reality — Criminalised by Design

A patient may lawfully: obtain a CBPM on prescription; carry it in the original container; drive with it under DVLA rules; and, where permitted, travel internationally. **Yet the moment they smoke their medicine—often the only route fast enough—they become a criminal.** No other prescribed patient group is placed in this position.

1.5 Bottom line

The question isn't whether smoking cannabis has risks; so do tobacco, alcohol, opioids, ketamine and benzodiazepines. The question is whether an **absolute, unevidenced** route ban that **uniquely** criminalises disabled patients can stand. It cannot. Reform is required.

2.0 Introduction

2.1 Purpose

This briefing explains how **Regulation 16A(3)**—a route-specific carve-out—**hollowed out** the 2018 reform, excludes a class of patients from effective treatment, and exposes government to legal, policy, and reputational risk. It situates the prohibition in its legislative, clinical, and human rights context, and highlights the structural discrimination created by criminalising the only route that, for some patients, can restore function quickly enough to prevent escalation.

A Reform That Wasn't: Ministers heralded access to cannabis medicines in 2018. **Regulation 16A(3) hollowed out that promise**, excluding patients for whom smoking is clinically necessary. **Permission in theory; prohibition in practice.**

2.2 Political and legislative context

- **2018 rescheduling.** Following high-profile child epilepsy cases, ministers enabled specialist prescribing of CBPMs.
- **Hidden limitation.** The amending regulations inserted **Regulation 16A(3),** stating: *"A product is not a cannabis-based product for medicinal use in humans if it is smoked."* No evidence was provided; the rationale for this provision was simply that "smoking will never be acceptable." This provision is often paraphrased as a definition of what a CBPM is not, but in practice it operates as a stand-alone prohibition that removes an otherwise lawful route of prescription use. The restriction was introduced without consultation or evidenced assessment of its clinical impact. – ***Editorial update highlighted to broaden explanation***
- **Seven years on.** NHS prescribing remains rare; private prescribing predominates. Patients who clinically need smoking for rapid relief are pushed into illegality, despite being in lawful possession of their prescribed medicine.

2.3 Legal frame

- **MDA 1971 / MoDR 2001:** establish prohibition unless exempted; **prescriptions are intended to be one such exemption.**
- **Equality Act 2010:** requires removal of barriers; the smoking ban **creates** one.
- **HRA 1998:** engages Article 8 (private life/autonomy) and Article 14 (non-discrimination); an **absolute ban** is hard to justify where less-restrictive alternatives exist.
- **Public law standards:** decisions must be evidence-based, proportionate, and procedurally fair — none of which apply here.

2.4 Methodology

This briefing uses a structured lens framework. While "lensing" is not a codified legal doctrine, the practice of testing the same measure against multiple analytical perspectives is well established in both law and policy. Courts regularly examine legislation through overlapping grounds such as proportionality, equality, and procedural fairness. Policy reviews apply different frames — economic, clinical, equality, or international — to assess the same issue. In public health and social policy, terms such as "disability lens" or "health lens" are widely used to highlight differential impacts. This briefing adopts a similar structure.

Each section therefore returns to the same statutory carve-out — Regulation 16A(3) — but applies a distinct perspective. What may appear at first as repetition is intentional: it demonstrates that the prohibition is not merely flawed in one respect, but unlawful and unsustainable across every relevant domain.

The sequence of lenses is as follows:

- **Section 3 — Statutory lens:** how Regulation 16A(3) fits within the Misuse of Drugs Act and Regulations.
- **Section 4 — Clinical lens:** why route of administration matters, and why smoking is uniquely necessary for some patients.
- **Section 5 — Comparative legislative lens:** how cannabis compares to other medicines and substances in UK law.
- **Section 6 — Constitutional lens:** the principle of residual liberty and the "double inversion" created by Regulation 16A(3).
- **Section 7 — Systemic lens:** how the prohibition manufactures its own justification and blocks prescribing.
- **Section 8 — Rights-based lens:** Equality Act and Human Rights Act implications.
- **Section 9 — Evidential lens:** the harm data available in 2018 but ignored by government.
- **Section 10 — Reasonableness lens:** how the prohibition fails domestic standards in public law, equality law, and clinical practice.
- **Section 11 — Procedural lens:** absence of consultation, equality assessment, or review.
- **Section 12 — Experiential lens:** real-world impacts on patients, clinicians, law enforcement, and society.
- **Section 13 — Policy lens:** contradictions across health, drug control, equality, and public health priorities.
- **Section 14 — International lens:** how peer jurisdictions regulate smoking rather than prohibit it.

- **Section 15 — Integrative conclusion:** bringing all lenses together to show the prohibition is indefensible and setting out remedies available to government.

3.0 Statutory Framework

Applying the statutory lens, this section sets out how Regulation 16A(3) sits within the Misuse of Drugs Act and Regulations.

3.1 Misuse of Drugs Act 1971

The Misuse of Drugs Act 1971 (MDA) provides the primary criminal framework for controlled drugs. Production, possession, and supply are offences unless an exemption applies through secondary legislation. Parliament deliberately left scope for lawful medical access to be created via regulation.

3.2 Misuse of Drugs Regulations 2001 (as amended 2018)

The Misuse of Drugs Regulations 2001 (MoDR) specify when controlled drugs may be lawfully possessed, supplied, and used (e.g. by prescription, licence, or research). In November 2018 the Regulations were amended to create a new category of cannabis-based products for medicinal use in humans (CBPMs), which can be prescribed by specialist doctors.

3.3 Regulation 16A(3): Route-specific exclusion

Regulation 16A(3) inserted by the Misuse of Drugs (Amendments) (Cannabis and Licence Fees) Regulations 2018 (SI 2018/1055) states in full: “Nothing in these Regulations shall authorise the smoking of cannabis, or the supply of cannabis for the purpose of being smoked.” This wording forms the operative statutory basis of the smoking prohibition. The Explanatory Memorandum described this as a clarification measure, though it was in effect a new limitation on the scope of lawful prescribing under the 2018 framework. – ***Editorial update to broaden explanation***

This means the same prescribed medicine is lawful if taken orally or vaporised, but criminal if smoked. The clinical consequences of this divide are summarised in Table 1.

Table 1: Routes of Administration — Onset, Duration, and Legal Status

Route	Onset	Duration	Typical Clinical Use	Legal Status under 16A(3)
Oral oils/capsules	30–90 min	4–8 h	Baseline / maintenance	Permitted
Vaporisation	5–15 min	2–4 h	Episodic symptom control	Permitted
Smoking	Seconds (first puff)	Up to 2 h	Fastest relief / breakthrough symptoms	Prohibited

Table 1 - Routes of Administration

3.4 Explanatory materials (2018)

The Explanatory Memorandum accompanying SI 2018/1055 offered no evidence base to justify a ban on the smoked administration, stating only that ***"smoking will never be acceptable".*** and made no reference to any impact or equality assessment. (A brief de minimis Impact Assessment was later located online but was not referenced in the Memorandum and omitted any equality or clinical analysis.) No consultation was undertaken with patients prior to the ban's introduction. A fuller analysis of the Memorandum and these omissions is provided in Section 11 (Procedural Irregularities).
Editorial update highlighted to broaden explanation

3.5 Interaction with adjacent frameworks

- Equality Act 2010: the route ban erects barriers for disabled patients.
- Human Rights Act 1998: engages Article 8 (autonomy/private life); an absolute ban is hard to justify when less restrictive alternatives exist.
- Human Medicines Regulations 2012: regulate quality, safety, authorisation and supply of medicines, but impose no route-specific bans. The only statutory route ban in UK medicines law applies uniquely to smoked CBPMs.

3.6 Drug-law Inversion and cannabis exceptionalism

In the UK, our primary constitutional principle is described as "residual liberty": everything is permitted unless prohibited. Drug law inverts this: conduct is prohibited unless expressly permitted. Cannabis goes further still. **Even when prescribed**, smoking remains criminalised. This creates a "double inversion" — prohibition layered within permission. The constitutional implications of this anomaly are developed in Section 6.

Figure 1: How Cannabis goes beyond the drug-law inversion

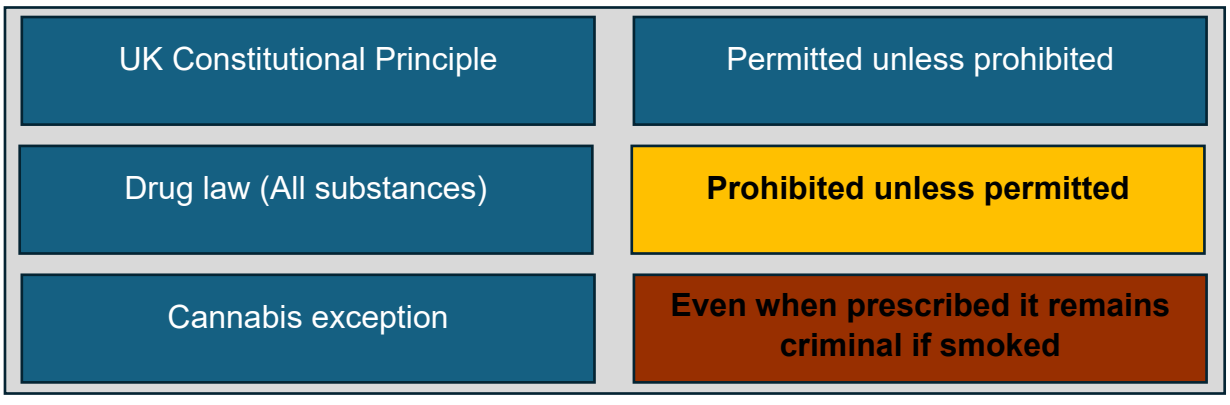

Figure 1 - Beyond Drug Law inversion

The UK's constitutional default is freedom unless prohibited. Drug law reverses this. Cannabis goes further still: smoking remains criminal even when prescribed.

3.7 Comparative legal anomalies

Where UK law departs from the permissive model, it is normally in contexts tied to national security or public safety, with clear licensed routes for lawful access. CBPMs stand out as the only case where prohibition is absolute: no licensed route exists for patients who need to smoke their prescription to medicate effectively.

*(See **Section 6** for further analysis of how this distinction operates in practice.)*

Domain	Default Legal Position	Nature of Inversion	Licensed Routes?	Purpose of Inversion
Firearms	Possession/use permitted unless prohibited	Prohibited unless licensed	Yes – firearms certificate	National security / public safety
Explosives	Manufacture/possession prohibited	Prohibited unless licensed	Yes – licensing regimes	National security / public safety
Nuclear materials	Possession/use prohibited	Prohibited unless licensed	Yes – state licensing	National security / strategic control
CBPMs (general)	Lawful if prescribed	Prohibited unless licensed	Yes – oils, capsules, vaporisers	Public health framing
CBPMs (smoking)	Lawful if prescribed, except when smoked		No – no licensed route	Unique anomaly – treated as if national-security risk

Table 2 - Legal inversion of the permissive principle

3.8 Comparison with other Schedule 2 medicines

Other Schedule 2 medicines may be misused outside prescribed routes, but such conduct is treated as clinical misuse, not a statutory offence. Cannabis is the only case where statute creates an offence based purely on route of administration. A full comparison is set out in Section 6.

(Section 6 examines the implications of this unique carve-out in constitutional and equality terms.)

3.9 Practical compliance burdens of 16A(3)

- The route-specific ban creates practical contradictions for patients, clinicians, and law enforcement. These systemic burdens are explored in detail in Section 6 & Section 7.

Precision Matters — Omissions and Carve-outs

UK law is built on residual liberty: everything is permitted unless prohibited. Drug law reverses that. Cannabis goes further still: a **route ban within a prescription**. This is not a feature of medicines law generally; it is a **cannabis-only anomaly**.

3.10 Summary

The 2018 reforms created lawful access in principle. Regulation 16A(3) withdrew it in practice for patients who need the fastest onset of relief. This carve-out is unique in UK medicines law and underpins the equality, clinical, and procedural issues developed in Sections 4–14.

Although both the Order and the Regulations were laid on 1 November 2018, they proceeded under different procedures. The affirmative Order, which created the lawful route for CBPMs, was debated in Parliament. The negative Regulations, which inserted Regulation 16A(3), were treated as consequential and therefore not subject to equivalent scrutiny or amendment. As a result, the specific prohibition on smoking was never examined on its own merits within parliamentary debate, despite its substantive effect on patient access. – ***Editorial update to broaden explanation***

Secondary legislation receives far less democratic scrutiny, typically via negative or affirmative resolution, meaning Parliament never debated the criminalisation of this route in full.

4.0 Clinical & Scientific Context

Using the clinical lens, this section shows why route of administration matters and why smoking is uniquely necessary for some patients.

4.1 Clinical indications and access reality

CBPMs are prescribed for a range of conditions, **including but not limited to** refractory epilepsy, breakthrough pain, severe nausea, spasticity, and neurological disorders. NHS prescribing remains extremely rare; most patients obtain access through **private clinics**.

For many patients, slower routes such as oils or vaporisation are **clinically useful and effective** for maintenance or episodic symptom control. But for those experiencing **sudden, acute episodes** — where treatment must act within seconds — these routes are not sufficient. In such cases, the absence of a lawful smoking option denies access to the **only route that can deliver relief immediately, often from the first puff, preventing escalation before symptoms peak**.

4.2 Pharmacokinetics, titration, and clinical need

Different routes deliver different **speeds of onset**, **durations of effect**, and degrees of **titration control**. Equally important is whether a patient can physically self-administer during crisis.

- **Oils/capsules**: onset 30–90 minutes; duration 4–8 hours. Titration is imprecise, and, once ingested cannot be adjusted. Useful for maintenance, not sudden escalation.
- **Vaporisation**: onset 5–15 minutes; duration 2–4 hours. Some titration possible, but requires a functioning device, preparation, and dexterity — often difficult for patients with tremor, reduced coordination, or sudden attacks. Relief may arrive only after symptoms have peaked.
- **Smoking**: onset **within seconds, often from the first puff**; duration up to 2 hours. Allows immediate titration — patients can stop after one or two inhalations once relief is achieved. Minimal dexterity is required, making it viable during acute neurological episodes or breakthrough pain.

(Table 1 in Section 3.3 sets out the basic pharmacokinetic comparison; this section expands it to titration and usability.)

4.3 Comparative risk and proportionality

Other substances with higher or comparable risk profiles are lawfully available without route-specific prohibitions. The singling out of cannabis smoking is therefore disproportionate:

- **Tobacco:** lawfully sold despite no medical benefit and overwhelming health harms.

- **Alcohol**: lawfully sold despite no therapeutic benefit, high addiction risk, and major social and health harms.
- **Opioids, benzodiazepines, ketamine**: prescribed despite high risks of dependency, overdose, and misuse; no route-specific bans are imposed.
- **Cannabis (smoked)**: carries risks of respiratory irritation and exposure to combustion toxins, but these are not uniquely high. However, published harm-ranking studies consistently placed cannabis below alcohol and tobacco in overall harm. (e.g. Nutt et al., *Lancet*, 2010 – See Annex A 1) Such risks are manageable through clinical guidance, regulation, and patient education**.**

Figure 2: Relative Risk Spectrum

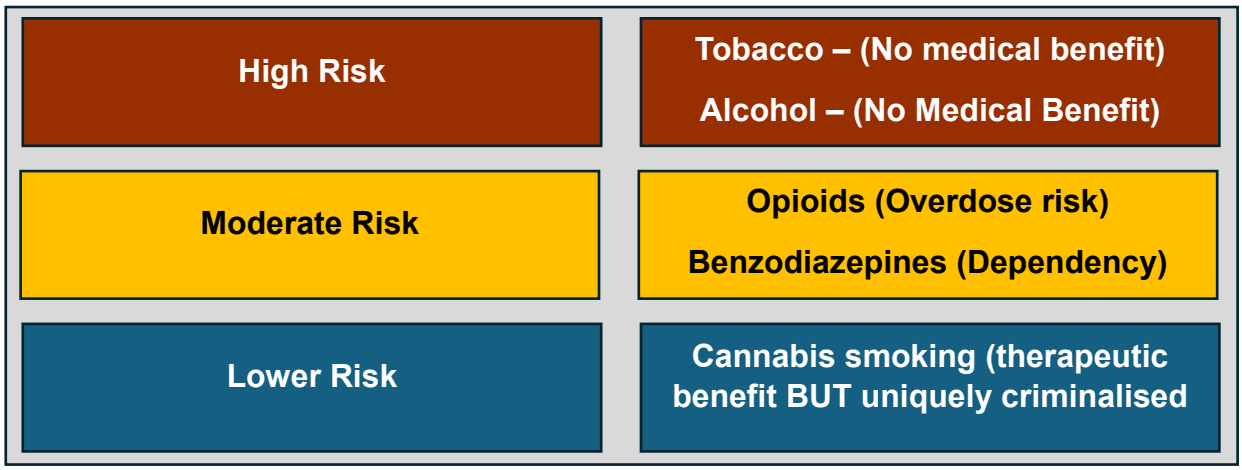

Figure 2- Relative Risk Spectrum

Cannabis smoking sits lower on the risk spectrum than tobacco and alcohol, and comparable to or below other high-risk medicines, yet it is the only route categorically prohibited in law.

4.4 NICE, MHRA and professional guidance

- **NICE (2019):** NICE recommended restricted prescribing based on limited evidence, but made no recommendation on route of administration, nor did it propose prohibition.
- **MHRA:** Regulates medicines for safety/quality; has never imposed a route ban.
- **Royal Colleges:** Urged caution, but without evidence for an absolute prohibition.
- **International comparators:** Canada, Germany, Israel, and many US states regulate medical smoking instead of banning it.

4.5 Vaping vs smoking — clinical limitations

Vaping is sometimes presented as a substitute, but for acute conditions:

- **Onset mismatch**: 5–15 minutes (too slow for crises that escalate in seconds).
- **Overshoot risk**: patients inhale more than they need whilst waiting, causing sedation, nausea, dizziness.
- **Dexterity barrier**: loading/operating a vape device can be impossible during seizures, tremors, or sudden neurological onset.
- **Smoking advantage**: relief **within seconds**, minimal dexterity, and controllable titration (a puff or two may suffice).

Clinical Necessity — When Seconds Count

In a sudden attack, even a 2-minute delay can be too late. **Oils are far too slow. Vaping helps, but requires time and dexterity that patients in crisis often don't have.**

Smoking can restore within seconds, often from the first puff, with immediate titration control. Denying this route forces patients into either therapeutic failure or unlawful use. The law creates a false choice between **ineffectiveness** and **criminality**.

5.0 Legislative Comparisons

Through the comparative legislative lens, this section contrasts cannabis with other medicines and substances in UK law.

5.1 Internal consistency (within medicines law)

Controlled drugs such as **morphine**, **benzodiazepines**, **ketamine**, and **stimulants** are managed through scheduling, prescription controls, and clinical discretion. None are restricted by **route-specific prohibitions**. The carve-out in Regulation 16A(3) is therefore an **outlier within medicines law itself**.

5.2 External comparators (outside medicines law)

The contradiction is starker when comparing cannabis smoking to other legally regulated substances:

- **Tobacco:** freely available for smoking, despite **no medical benefit** and status as the leading preventable cause of death.
- **Alcohol:** freely available for consumption, despite **no medical benefit**, widespread addiction, and profound health and social harms.
- **Opioids:** permitted for prescription, including high-risk administration routes (e.g. intravenous), without any categorical prohibition.
- **Benzodiazepines:** prescribed despite dependency risks; no route-specific restrictions.
- **Ketamine:** a Schedule 2 controlled drug; lawfully available by injection, oral, and nasal spray. In practice, it can be misused in multiple ways (e.g. insufflation, injection of diverted liquid, or covert administration). Such misuse is treated as clinical misuse or unlawful supply, not as a separate crime based on route of administration.
- **Cannabis (CBPMs)**: lawful if prescribed and consumed orally or vaporised; **criminal** if smoked, even when prescribed for therapeutic need.

Table 3: Legal Comparators — Smoking, Risk, and Benefit

Substance/Medicine	Smoking/Use Permitted?	Medical Benefit?	Legal Status	Note
Tobacco	Yes	None	Legal	Leading preventable cause of death
Alcohol	Yes (consumption)	None	Legal	Major morbidity and social harm
Morphine	Yes (incl. IV/high-risk)	Significant	Legal (controlled)	No route ban
Benzodiazepines	Yes (any route)	Significant	Legal (controlled)	Dependency risk
Ketamine	No smokable form prescribed	Significant	Legal (controlled)	Misuse treated clinically, not as separate crime
Cannabis (CBPMs)	**No (if smoked)**	**Significant**	**Legal if prescribed**	**Smoking uniquely criminalised**

Table 3 - Legal comparators

5.3 Comparative Evidence

Comparative scientific evidence reinforces these legal anomalies. Peer-reviewed multicriteria analyses (Nutt et al., 2010; van Amsterdam et al., 2015) ranked cannabis among the least harmful substances, with alcohol and tobacco far higher in overall harm.

The government had access to these findings when enacting Regulation 16A(3), yet chose to prohibit smoking for medicinal use while continuing to permit more harmful substances without route bans. The full rankings are reproduced in Tables 1 and 2 at Annex A.

This evidential context sharpens the proportionality argument: the statutory carve-out of Regulation 16A(3) runs directly counter to the harm data available to government when the 2018 amendment was made.

Government and ACMD materials made no use of available MCDA or harm comparative evidence in designing the 2018 framework, and the Impact Assessment subsequently identified in Annex D contained no reference to those datasets or any quantitative harm analysis of CBPM use. See Annex D. – ***Editorial update to broaden explanation***

5.4 Consequence of the comparison

- **Tobacco/alcohol**: permitted despite **no medical benefit**.
- **High-risk medicines (opioids, benzos, ketamine)**: permitted under **clinical discretion**, no route bans.
- **Cannabis**: therapeutic, safer than tobacco/alcohol, but **singled out for prohibition** by route.

The Sole Exception

Every other high-risk medicine relies on **clinician discretion** and regulatory safeguards. **Only cannabis** is partly criminal even when prescribed — and only if smoked. This anomaly cannot be defended in law, evidence, or policy.

6.0 Prohibited Unless Permitted

Applying the constitutional lens, this section examines how Regulation 16A(3) creates a double inversion of the UK's residual liberty principle.

6.1 The constitutional principle in UK law

A foundational principle of the UK legal order is that citizens are free to act unless their conduct is expressly prohibited by law. This residual liberty principle underpins both criminal law and wider constitutional tradition: freedom is the default; restriction requires explicit legislative justification.

6.2 The inversion in drug control law

Drug law displaces this principle. Under the Misuse of Drugs Act 1971 and the Regulations 2001, conduct is prohibited unless expressly permitted. All possession, supply, and use of controlled drugs are unlawful unless a specific exemption applies (e.g. prescription, licence, or research).

6.3 Cannabis: prohibition within permission

As illustrated in Figure 1 (Section 3.6), cannabis goes further still. Even when prescribed, smoking remains criminalised. This creates a *double inversion*: the UK's constitutional principle is reversed by drug law, and cannabis is uniquely carved out so that even when permitted, it is still prohibited.

6.4 Technical misuse vs statutory prohibition

For most medicines, altering the route of administration is technically outside the prescription exemption ("in accordance with the directions of a practitioner"), but in practice treated as clinical misuse, not a criminal offence. Cannabis is the only case where statute makes the route itself a crime and remains the only medicine for which a specific route of administration — smoking — is explicitly criminalised in law. No equivalent limitation applies to any other controlled drug. *(See annex D)* ***Editorial update to broaden explanation***

Table 4: Altered Routes — Clinical Misuse vs Statutory Prohibition

Substance	Typical Prescribed Route(s)	Common Misuse Route(s)	Explicit Statutory Prohibition?	Legal / Clinical Consequences
Opioids (e.g. morphine)	Oral, patches, injection	Crushed and snorted/injected	No	Treated as misuse; clinically unsafe; not prosecuted if self-use
Methylphenidate	Oral tablets/capsules	Taken intranasally	No	Clinical misuse; may lose prescription; not a statutory offence
Benzodiazepines	Oral tablets/solution	Crushed, injected, or dissolved illicitly	No	Dependency risk; misuse; not a statutory offence
Ketamine	Injection, oral, nasal spray	Snorted, injected from diverted liquid, covert administration	No	Misuse or unlawful supply; prosecution only for diversion/other offences
CBPMs (cannabis-based medicinal products)	Oils, capsules, vaporiser	Smoked	Yes – Regulation 16A(3)	Always a criminal offence, even if prescribed

Table 4- Altered Routes

For all other Schedule 2 medicines, altered routes are treated as misuse. Cannabis alone is explicitly criminalised by statute if smoked.

6.5 Consequences of inversion and carve-out

- Patients: forced into unlawful behaviour to achieve effective treatment.
- Clinicians: prevented from recommending the clinically optimal route, undermining professional judgment.
- Law enforcement: left policing prescriptions that are lawful by one route but criminal by another.
- Legal system: required to enforce contradictions that cut against proportionality, equality, and constitutional principle.

Permission That Isn't Permission

In UK law, a prescription always makes treatment lawful. Except here. For cannabis, prescription is conditional: lawful by one route, criminal by another. This contradiction is unique and indefensible.

6.6 Summary

The constitutional principle in the UK is freedom unless prohibited. Drug law inverts that: prohibited unless permitted. Cannabis goes further still: even when expressly permitted, it remains prohibited by route. This structural contradiction makes Regulation 16A(3) legally and constitutionally vulnerable.

7.0 Access Blockages and the Circular Policy Trap

Using the systemic lens, this section shows how the prohibition manufactures its own justification and blocks prescribing and evidence gathering.

7.1 The promise of 2018

When Parliament amended the Misuse of Drugs Regulations in 2018, the stated aim was to enable patients with serious conditions to access cannabis-based medicines under specialist prescription. Families and campaigners were told that legal access had been created.

7.2 The reality of prescribing

- **NHS prescribing**: still extremely rare; only a handful of cases, mainly paediatric epilepsy.
- **Private prescribing**: where most patients obtain treatment, often at significant personal cost.
- **Specialist barrier**: only consultants on the GMC register may prescribe, sharply reducing availability.
- **Chilling effect:** clinicians fear reputational and regulatory sanction, discouraging even those sympathetic to prescribing.

7.3 The smoking prohibition as a systemic block

For patients who require smoking for acute relief, the prohibition is not incidental but a **systemic exclusion**:

- **Patients:** conceal their route of use to avoid losing prescriptions, distorting the clinical relationship.
- **Clinicians:** cannot lawfully recommend or monitor the fastest and most effective route.
- **Researchers:** have no pathway to study smoking in practice, preventing data collection.
- **Regulators:** bodies such as NICE, MHRA, GMC, and CQC are paralysed, unable to develop guidance on a route that the law criminalises.

7.4 The circular trap

The regulatory structure creates a **self-reinforcing cycle**:

1. Government asserts there is no evidence base to support smoking cannabis.
2. The law prohibits smoking cannabis, preventing evidence from being gathered.
3. Clinicians are unable to form a responsible body of opinion because the route is criminal.
4. Government points to the absence of evidence and clinical consensus as justification for continuing prohibition.

This circularity means that **patients are excluded by design**.

Figure 3: The Circular Policy Trap

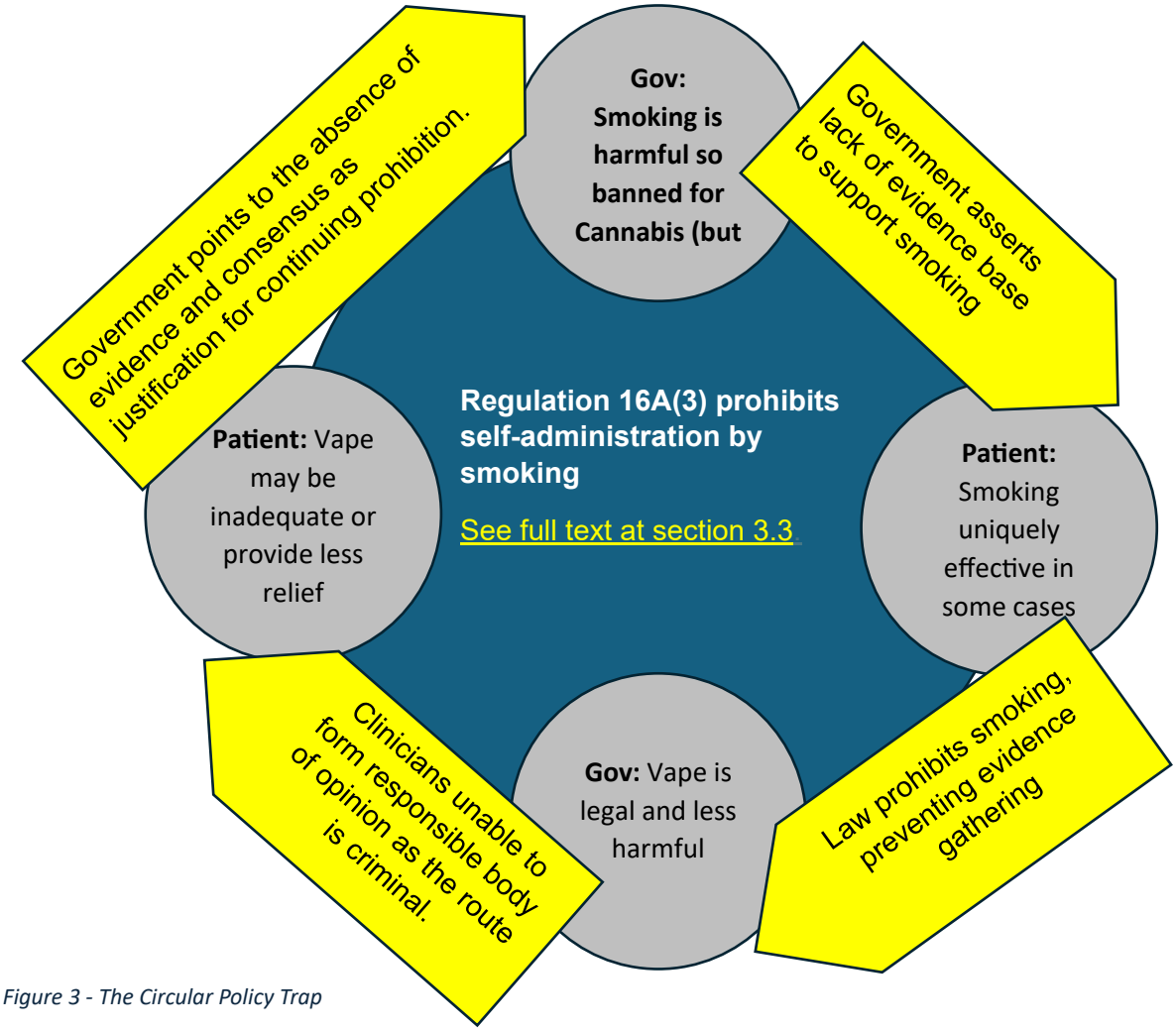

Figure 3 - The Circular Policy Trap

The prohibition manufactures its own justification, locking patients out of both treatment and evidence.

7.5 Consequences of the trap

- **Patients**: excluded from effective treatment; criminalised if they self manage.
- **Clinicians**: silenced from developing or voicing professional opinion due to the illegality of smoked consumption.
- **Researchers**: barred from generating the very data government demands due to the illegality of smoked consumption.
- **Policy-makers**: rely on absence of evidence that is structurally engineered.
- **Equality impact:** disabled patients who need the fastest onset of relief are uniquely disadvantaged, compounding discrimination identified in Section 6.

A System That Feeds Itself

Evidence is demanded but blocked. Prescribing is promised but denied. Clinical judgment is required but prohibited. The system is self-fulfilling: **no evidence, no prescribing, no change**. Patients are left trapped between ineffectiveness and criminality.

8.0 Rights and Freedoms

Through the rights-based lens, this section applies the Equality Act and Human Rights Act to demonstrate unlawful discrimination.

8.1 Equality Act 2010

The Equality Act imposes a duty to make reasonable adjustments where a provision, criterion, or practice places disabled people at a substantial disadvantage. Regulation 16A(3) does the opposite: it creates a disadvantage for patients who can only achieve functional relief through smoking.

- **Direct discrimination:** Though framed neutrally, the prohibition functions to exclude a defined group — disabled patients needing the fastest onset of relief.
- **Indirect discrimination**: a policy applied to all, but which disproportionately excludes disabled people with sudden-onset conditions.
- **Failure to adjust:** clinicians cannot lawfully prescribe the most effective route, denying patients any chance of accommodation.

As demonstrated in Section 7.4, this systemic trap compounds disadvantage and entrenches unequal treatment.

8.2 Human Rights Act 1998

The HRA incorporates the European Convention on Human Rights into UK law.

- Article 8 (private life, autonomy, dignity): engaged where patients must choose between medical effectiveness and criminality.
- Article 14 (non-discrimination): engaged because only patients needing smoking face exclusion, unlike patients prescribed other high-risk medicines.
- Article 3 (inhuman or degrading treatment): may be engaged where patients are forced into avoidable suffering by denial of the only effective route.

8.3 Proportionality and necessity

Under ECHR analysis, interferences with rights must be:

1. In pursuit of a legitimate aim;
2. Rationally connected to that aim;
3. The least restrictive means available;
4. A fair balance between individual rights and the public interest.

The prohibition fails these tests:

- **Aim:** protecting health is legitimate, but
- **Connection:** banning smoking undermines health by denying effective treatment;
- **Least restrictive means:** regulation, clinical guidance and patient education are available alternatives;
- **Balance:** the burden falls entirely on disabled patients, with negligible public benefit.

No equality impact assessment or consultation was undertaken before enacting the ban (see Section 3.4), further undermining any claim that it was necessary or proportionate. This prohibition was imposed without consultation or equality impact assessment, and imposed through secondary regulation, making it doubly difficult to defend against rights challenges.

8.4 International comparators

Other jurisdictions regulate smoking where clinically indicated, showing that less restrictive approaches are feasible:

- **Germany:** dried-flower cannabis is reimbursed, smoking not prohibited.
- **Canada:** permits smoking under medical supervision, regulates product quality.
- **Israel:** allows smoking where clinically appropriate.
- **US states** (e.g. California, Colorado): regulate rather than prohibit smoking for medical use.

None of these jurisdictions has reported public health harms justifying an absolute prohibition.

8.5 Summary

Regulation 16A(3) is irreconcilable with both domestic equality duties and international human rights standards. It forces patients to choose between ineffectiveness and illegality, a choice not demanded of any other patient group.

Rights Withheld

The Equality Act requires barriers to be removed. The Human Rights Act requires proportionality. International practice shows regulation is possible. Yet Regulation 16A(3) does the reverse: it imposes barriers, rejects proportionality, and isolates the UK internationally.

9.0 Ignored Evidence on Relative Harms

Applying the evidential lens, this section shows how government ignored comparative harm data that was available in 2018.

9.1 Origins of the harm framework

In 2007 the Home Office commissioned a harm-ranking exercise which laid the foundations for a systematic assessment of the relative harms of different drugs (Advisory Council on the Misuse of Drugs, 2007). That work, undertaken by government advisers including Professor David Nutt, used nine criteria to compare substances and highlighted inconsistencies in the existing classification system.

Following his dismissal as Chair of the Advisory Council on the Misuse of Drugs (ACMD) in 2009, Professor Nutt and colleagues refined and expanded the model. In 2010 they published a landmark study in *The Lancet* using a transparent Multicriteria Decision Analysis (MCDA) methodology across 16 criteria (Nutt et al., 2010). Although not formally commissioned by government, the 2010 study represented a direct continuation of government-initiated work, produced by the very experts who had been statutory advisers to ministers months earlier. The model was subsequently validated by a Europe-wide expert panel in 2015, which confirmed the robustness of the UK findings (van Amsterdam et al., 2015).

9.2 Findings of the UK and EU studies

- The **2010 UK study** ranked 20 drugs on harms to users and to society. Alcohol, heroin and crack cocaine scored highest overall (72, 55 and 54 respectively). Tobacco (26) was significantly more harmful than cannabis (20) (Nutt et al., 2010).
- The **2015 EU expert panel study**, involving 40 senior experts across Europe, replicated the methodology and produced near-identical results (correlation ≈ 0.99). Again, cannabis sat in the lower tier of overall harm, far below alcohol and tobacco (van Amsterdam et al., 2015).
- These findings were widely publicised, debated in Parliament, and remain among the most cited pieces of comparative evidence on drug harms.

9.3 Availability of evidence by 2018

By the time the 2018 amendment to the Misuse of Drugs Regulations was drafted, government officials had:

- The **UK-originated harm model**, commissioned initially by the Home Office in 2007.
- The **refined 2010 Lancet study**, published by former ACMD members (Nutt et al., 2010).

- The **EU-wide validation in 2015**, confirming the robustness of the findings (van Amsterdam et al., 2015).

These were not marginal studies: they were peer-reviewed, widely reported, and directly relevant to the question of proportionality in regulating cannabis-based products.

The comparative harm rankings developed by Nutt et al. (2010) and validated by van Amsterdam et al. (2015) provide the clearest quantitative evidence of relative risks. Both placed cannabis well below alcohol and tobacco in overall harm. These findings were widely known and available to government by 2018, yet neither the ACMD advice nor the Explanatory Memorandum engaged with them. The full rankings are reproduced in **Annex A, Tables 1 and 2**. See also **Annex B** for more recent research and associated research gaps.

9.4 Government's omission

Neither the Explanatory Memorandum to the 2018 amendment nor the underlying ACMD advice addressed these harm rankings. No attempt was made to reconcile the decision to criminalise smoked CBPMs with the well-established evidence that cannabis was among the least harmful substances in comparative terms, especially when set against alcohol and tobacco which remain lawfully available.

9.5 Consequence for lawfulness

The omission of this material evidence demonstrates:

- **Procedural irregularity** – a failure to take into account relevant considerations.
- **Substantive unreasonableness** – treating cannabis as uniquely dangerous despite evidence to the contrary – on a par with national security but lacking relevant permissive safeguards.
- **Disproportionality** – imposing an absolute statutory ban on one route of administration of a comparatively low-harm substance, while tolerating routes of use for far more harmful substances.

9.6 Political discontinuity and institutional failure

The history of the harm-ranking model illustrates a deeper systemic problem. The framework was first developed in 2007 under Home Office commission, and Professor David Nutt was subsequently appointed Chair of the ACMD under the Labour government. In 2008–09 cannabis was temporarily downgraded to Class C, reflecting a degree of responsiveness to scientific advice, but only within tight political constraints.

When Professor Nutt publicly criticised ministers for disregarding evidence, he was dismissed from his post. The refined 2010 study in *The Lancet* was published independently as a direct continuation of that government-commissioned work (Nutt et al.,

2010). The episode revealed a striking **lack of continuity of evidence use across government**: expert advice was welcomed when politically convenient, discarded when inconvenient, and never properly embedded into policymaking structures.

By 2015, the methodology had been validated by a Europe-wide panel of 40 experts, confirming the UK findings almost exactly (van Amsterdam et al., 2015). By 2018, government had therefore had over a decade to integrate and reflect upon the evidence base it had itself initiated. The continuing absence of that evidence in the Explanatory Memorandum and ACMD advice is symptomatic of a **systemic failure of institutional memory and cross-party continuity**.

This background underscores that the omission of the harm rankings in 2018 was not an isolated oversight but part of a **longstanding pattern of closed thinking and political selectivity** in UK drug policy.

Ignored Evidence of Relative Harm

The government's own commissioned work in 2007 developed the harm-ranking model later published in *The Lancet* (Nutt et al., 2010) and validated across Europe in 2015 (van Amsterdam et al., 2015). By 2018, this evidence showed cannabis to be among the least harmful substances, far below alcohol and tobacco. Yet the Explanatory Memorandum and ACMD advice made no reference to it. The omission demonstrates closed thinking, failure to consider relevant evidence, and undermines the proportionality of Regulation 16A(3).

9.7 Political Selectivity and Institutional Failure

The harm-ranking model was born inside government in 2007, refined by former ACMD advisers in 2010, and validated across Europe in 2015. Yet because it proved politically inconvenient, it was never embedded into policy. Ministers dismissed the experts who developed it, and officials subsequently ignored its findings. By 2018, after more than a decade, the evidence base remained excluded — not because it was irrelevant, but because it was politically unwelcome. This demonstrates a systemic failure of continuity and an entrenched culture of closed thinking.

References

- Advisory Council on the Misuse of Drugs (2007). *Drug harms: a decision analysis*. Home Office.
- Nutt, D., King, L. A., & Phillips, L. (2010). *Drug harms in the UK: a multicriteria decision analysis*. The Lancet, 376(9752), 1558–1565.
- van Amsterdam, J., Nutt, D., Phillips, L., & van den Brink, W. (2015). *European rating of drug harms*. Journal of Psychopharmacology, 29(6), 655–660.

10.0 Reasonableness Tests Across Law

Through the reasonableness lens, this section tests the prohibition against domestic standards in public law, equality law, and clinical practice.

10.1 Shared legal principle

Across multiple branches of law, **reasonableness** is the yardstick by which conduct, decisions, and duties are judged. Whether in public law, clinical practice, equality legislation, or criminal law, the principle provides a common measure of fairness, proportionality, and legitimacy.

10.2 Application to smoking prohibition

The prohibition on smoking CBPMs can be examined against these recognised standards of reasonableness. The comparison demonstrates two consistent outcomes:

- Under several tests, the prohibition fails outright.
- Under others, the regulation itself makes it impossible for the test to be applied, since it prevents clinicians or patients from ever meeting the threshold of "reasonableness."

Table 6: Reasonableness Tests and their Application to the Prohibition on Smoking CBPMs

Each test is set out below with cross-references to the relevant sections of this briefing where the underlying analysis is developed.

Test of Reasonableness	How it Normally Operates	Application to CBPMs	Constraint / Failure Point
Wednesbury (public law) *(Sect 3.4)*	A decision is unlawful if no reasonable authority could ever reach it.	A blanket prohibition irrespective of clinical need appears irrational when less restrictive regulatory options are available.	The decision risks being judged so unreasonable as to fall outside lawful discretion.
Proportionality (ECHR/HRA) *(Sect 8.3)*	Legitimate aim, rational connection, least restrictive means, fair balance between rights and public interest.	Prohibition is not the least restrictive means and fails to strike a fair balance where patients are disproportionately excluded.	Breach of proportionality under structured analysis.
Equality Act (reasonable adjustments) *(Sect 8.1)*	Duty to adjust practices and policies to avoid disadvantaging disabled people.	Some disabled patients can only benefit through smoking.	An absolute ban prevents any possibility of a reasonable adjustment.
Bolam/Bolitho (clinical practice)	A practice is reasonable if supported by a responsible body of medical opinion and withstands logical scrutiny.	Clinicians cannot form or voice such an opinion where the route is criminalised.	The regulation makes compliance with Bolam / Bolitho legally and clinically impossible.
Reasonable patient standard	A reasonable patient acts prudently in light of their circumstances and knowledge.	Patients choosing an effective route that restores function are acting reasonably.	The law criminalises what would otherwise be reasonable patient behaviour.

Table 6- Reasonableness Tests

10.3 Summary of failures

This comparative analysis shows that the prohibition cannot withstand scrutiny under any established test of reasonableness. Either it fails directly (as with proportionality or equality) or it suppresses the very conditions needed for reasonableness to be judged (as with Bolam/Bolitho). The regulation thus manufactures its own justification: it prevents evidence and clinical consensus from forming, and then relies on their absence to maintain prohibition. This prohibition not only entrenches the circular trap described in Section 7, but also fails every recognised legal and clinical standard of reasonableness. It exemplifies the structural discrimination at the heart of Regulation 16A(3).

When Law Forbids Reasonableness

Courts, clinicians, and patients are expected to act reasonably. Regulation 16A(3) blocks that possibility: **tests fail, not because patients or doctors are unreasonable, but because the law prohibits reason itself.**

11.0 Procedural Irregularities

Using the procedural lens, this section exposes how Regulation 16A(3) was imposed without consultation, equality assessment, or review.

11.1 Lack of consultation

When Regulation 16A(3) was introduced in 2018, no public consultation was held. Stakeholders — including clinicians, patients, regulators, and researchers — were not invited to provide evidence or comment. As noted in Section 3.4, the Explanatory Memorandum simply stated that "smoking will never be acceptable," without evidential support. This omission is highly irregular for a regulatory change with wide-ranging consequences for health, equality, and criminal law.

11.2 Absence of equality impact assessment

The government did not conduct or publish an **Equality Impact Assessment.** Yet the prohibition clearly engages the Equality Act 2010, as it disproportionately disadvantages disabled patients who rely on the fastest-acting route of administration (see Section 8.1). The absence of an assessment undermines the law's legitimacy and leaves it vulnerable to challenge.

A brief de minimis Impact Assessment (UKIA 20180129) was later located online, though it was not referenced in the Explanatory Memorandum and does not appear to have undergone RPC review. The IA contained no analysis of equality, clinical, or proportionality impacts and provided no quantitative evidence on patient effect or enforcement costs. Its existence does not alter the conclusion that the decision-making process failed to meet standard consultation and assessment expectations for secondary legislation with direct clinical impact. The absence of an Equality Impact Assessment and the omission of any patient or clinical consultation remain significant procedural deficiencies. The Regulations therefore departed from normal regulatory practice by introducing a novel limitation without transparent supporting analysis or external scrutiny. - ***Editorial update to broaden explanation***

11.3 Failure to review

Since 2018, no statutory or ministerial review has been conducted into the impact of Regulation 16A(3). Despite growing evidence of patient need, international comparators, and clinical practice abroad, the prohibition has remained unchanged. This failure entrenches the circular trap described in Section 7.4, where the lack of evidence is manufactured by the law itself. It also contrasts with repeated ministerial assurances that prescribing access would be kept under review.

11.4 Departure from regulatory norms

- **Medicines regulation (MHRA):** normally operates through proportionate safeguards (labelling, dosage, monitoring), not absolute bans on routes.
- **Controlled drug regulation (Home Office):** usually incorporates consultation with advisory councils (ACMD), evidence review, and expert input. None of these steps were followed for the smoking carve-out.
- **Other policy domains:** where risks exist (e.g. alcohol, tobacco, opioids), regulation is targeted and proportionate — not categorical prohibition.

11.5 Procedural impropriety

The cumulative effect is **procedural impropriety**:

- No consultation;
- No equality assessment;
- No review;
- No evidence base;
- Departure from established regulatory norms.

Such impropriety strengthens the argument that the prohibition is **unlawful in process as well as substance**.

A Rule Without a Process

The prohibition on smoking was imposed without consultation, without assessment, and without review. It bypassed the normal safeguards of regulatory decision-making. A rule without process is a rule without legitimacy.

12.0 Real-World Impacts

Through the experiential lens, this section documents how the prohibition affects patients, clinicians, law enforcement, employers, and public health.

12.1 Patients

- Forced to choose between ineffective lawful treatment and effective treatment that is criminalised.
- Conceal their actual route of use from clinicians, undermining safe prescribing.
- Live with fear of arrest, prosecution, or loss of employment if route is disclosed.
- Experience unnecessary hospitalisations when slower routes fail to prevent escalation (see Section 8 on disproportionate disadvantage to disabled patients; Section 9 on ignored evidence of relative harm.)

12.2 Clinicians

- Stripped of autonomy to recommend the most effective route.
- Forced into defensive practice: either withhold prescribing or turn a blind eye to smoking.
- Unable to contribute to an evidence base that could inform safer clinical practice.
- Face reputational or regulatory risk if associated with patients who smoke prescribed cannabis. (see Section 10.2 on Bolam/Bolitho)

12.3 Law enforcement and justice system

- Police encounter patients with lawful prescriptions whose use becomes unlawful by route.
- CPS and courts spend resources prosecuting conduct that is otherwise medically legitimate.
- Creates inconsistency: misuse of other prescribed medicines is treated as a matter of clinical management. Medicating with smoked cannabis is criminal by statute.
- Undermines public confidence in proportionality and fairness of the justice system. (see Section 6.4 & 6.5 on policing paradoxes).

12.4 Employment and social impacts

- Employers often impose disciplinary action if patients admit to smoking their prescribed medicine.
- Patients conceal their treatment, risking workplace safety and transparency.

- Families and carers bear added stress of supporting loved ones forced into illegality.
- Legal uncertainty for employers and carers: unclear whether smoking prescribed cannabis is medical use or misconduct.
- Stigma and discrimination are reinforced: cannabis patients marked out as “criminal” despite lawful prescriptions.

12.5 Public health consequences

- Evidence base suppressed: prohibition prevents collection of safety/efficacy data on smoking (see Section 7 on the circular trap; Section 9 on ignored harm evidence).
- Health inequalities widened: only wealthier patients may afford private prescriptions — and even then are excluded from smoking.
- Emergency admissions increased: preventable crises escalate when slower routes fail.
- International divergence: UK falls behind peer jurisdictions in regulatory science and clinical innovation.

12.6 Summary

Regulation 16A(3) imposes consequences far beyond the consultation room. It distorts clinical relationships, burdens law enforcement, undermines workplaces, suppresses evidence, and entrenches health inequalities. The result is not improved public health, but fear, secrecy, wasted resources, and deepened discrimination. These real-world harms underline the urgency of reform and set the stage for the recommendations that follow in **Section 15**

The Human Cost

The prohibition does not eliminate smoking. It only eliminates **lawful smoking**. Patients continue to do what works, but in fear, secrecy, and stigma. Clinicians stay silent. Police and courts waste resources. Employers punish. Families suffer. The human cost is high — and wholly avoidable.

13.0Policy Contradictions

Applying the policy lens, this section highlights contradictions across health, drug control, equality, and public health priorities.

13.1 Contradictions in health policy

- **Tobacco**: legal for smoking despite no medical benefit and being the leading cause of preventable death.
- **Alcohol**: freely available despite its health and social harms and absence of therapeutic value.
- **Opioids, benzodiazepines, ketamine**: prescribed despite high risks of dependency, overdose, and misuse — yet no route bans exist.
- **Cannabis**: therapeutic benefit recognised, but smoking uniquely criminalised even when prescribed.

(See Section 9 for the comparative harm evidence underpinning these contradictions.)

Cannabis is the only substance where medical benefit exists but smoking is prohibited by statute.

Figure 4: Policy Contradictions

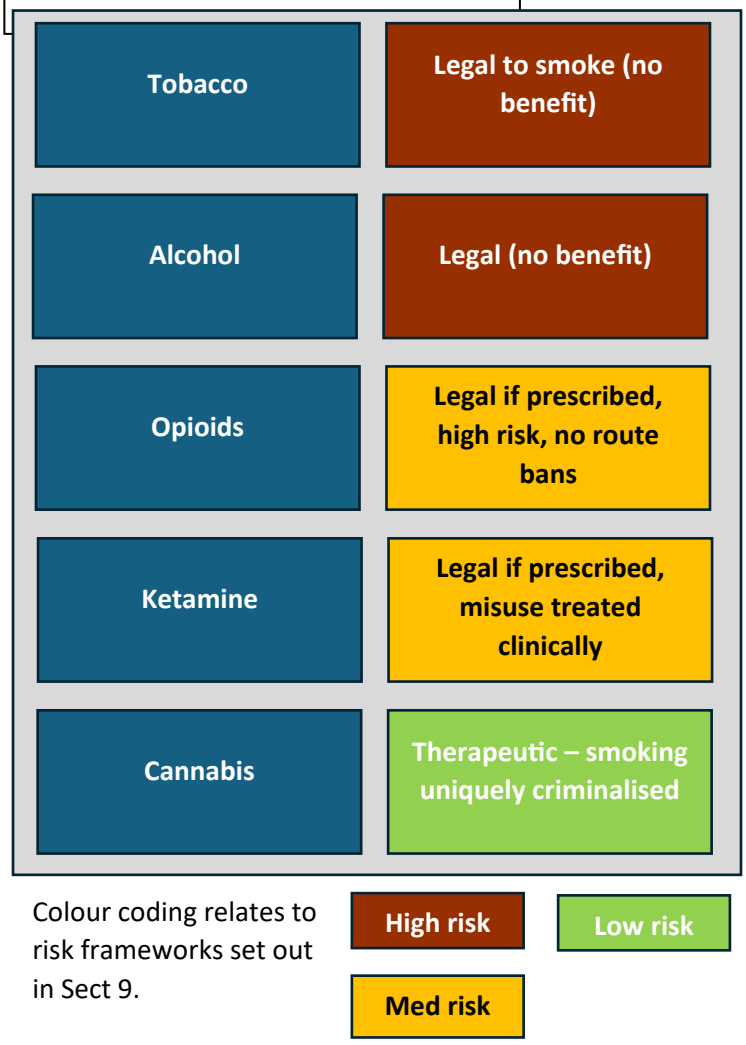

Figure 4 - Policy Contradictions

13.2 Contradictions within drug control policy

- **Misuse of Drugs Act 1971**: designed to prevent harm while permitting medical use under control.
- **MoDR 2001**: permit medical use of controlled substances, but carve cannabis smoking out of permission.
- **Police practice**: misuse of prescription opioids/ketamine treated as clinical misuse; cannabis smoking treated as statutory crime.

*(See **Section 6.4–6.5** on altered routes and policing paradoxes.)*

13.3 Contradictions within equality and disability policy

- Government policy commits to reducing health inequalities and supporting independent living.
- Regulation 16A(3) increases inequality by denying effective treatment to disabled patients needing fastest onset.
- Patients are punished not for misuse, but for choosing the only clinically effective route.

(See Section 8.1 on Equality Act duties.)

13.4 Contradictions in public health priorities

- **Harm reduction principle**: embedded across UK health policy (tobacco cessation, needle exchanges, safe consumption facilities).
- Cannabis smoking prohibition is the **opposite** of harm reduction: it drives patients into secrecy, unsafe practice, and criminalisation.

(See Section 7 on the circular trap and Section 12.5 on public health consequences.)

13.5 The principle of prohibition by exceptionalism

Cannabis smoking is criminalised not because of evidence, but because of exceptionalism. No other prescribable medicine is singled out for a statutory ban on its most effective route. This exceptionalism compounds the double inversion set out in **Section 3.6**, creating a prohibition-within-permission that exists nowhere else in UK medicines law. This makes Regulation 16A(3) not only anomalous, but discriminatory.

Prohibition by Exceptionalism

No other medicine is banned by route. Tobacco and alcohol are legal despite no medical benefit. High-risk medicines are permitted under clinical discretion. **Cannabis alone is prohibited by exceptionalism.**

14.0 Comparative Legal Analysis

Using the international lens, this section compares the UK's approach with peer jurisdictions and European human rights standards.

14.1 International norms

Many jurisdictions with established medical cannabis programmes permit smoking where clinically appropriate. The UK's route prohibition is therefore an international outlier.

- **Germany**: reimburses dried-flower cannabis; smoking not prohibited.
- **Canada**: regulates quality and permits smoking alongside oils and vaporisers.
- **Israel**: allows smoking under medical supervision; integrates into patient care.
- **United States (state level)**: in many states (e.g. California, Colorado, New York), smoking is permitted within regulated medical frameworks.

(See Section 4 for clinical comparators and Section 9 for ignored harm evidence.)

14.2 European human rights context

Under the **European Convention on Human Rights**, the prohibition conflicts with:

- **Article 8** (private life/autonomy): denying patients effective relief intrudes disproportionately.
- **Article 14** (non-discrimination): only disabled patients needing fastest onset are excluded.
- **Article 3** (inhuman or degrading treatment): arguably engaged where patients suffer avoidable deterioration because effective treatment is criminalised.

(See Section 8 for domestic analysis.)

14.3 Comparative proportionality

Other jurisdictions regulate smoking by:

- Limiting prescription to specific indications.
- Controlling dosage and supply chain.
- Educating patients on risk reduction.
- Monitoring long-term safety data.

These measures achieve legitimate aims (safety, health protection) without resorting to absolute bans. The UK prohibition is therefore neither proportionate nor necessary.

(See Section 8.3 on proportionality tests and Section 10 on reasonableness analysis.)

14.4 Comparative equality frameworks

- **Canada** and **Germany**: equality principles applied to ensure disabled patients are **not** disadvantaged by route limitations.
- **UK**: Regulation 16A(3) entrenches disadvantage, contrary to the Equality Act 2010 duty of reasonable adjustment.

(See Section 8.1 on Equality Act duties and Section 13.3 on domestic equality contradictions.)

14.5 Summary

The UK stands virtually alone in criminalising smoking of a prescribed medicine — an approach unsupported by evidence (Section 9), inconsistent with international comparators, and incompatible with domestic equality duties (Section 8). European human rights standards emphasise proportionality and non-discrimination. The UK approach is therefore legally vulnerable, clinically unjustified, and ethically indefensible.

Out of step with the world

Germany, Canada, Israel, US states — all regulate medical smoking where needed. The UK alone criminalises it. The result is not alignment with international best practice, but isolation and inequality.

15.0 Conclusions and Remedies

This final section integrates all the lenses, showing the prohibition is indefensible across every domain and identifying remedies available to government.

15.1 Core conclusion

Regulation 16A(3) creates a **unique anomaly in UK medicines law**: a prescribed medicine is lawful by some routes but criminal by another. This prohibition disproportionately harms disabled patients, undermines clinician autonomy, wastes public resources, and isolates the UK internationally. It cannot be reconciled with equality duties, human rights standards, or principles of proportionality. (see Sections 3.6, 6.3, and 14.3)

15.2 Structural discrimination

The prohibition is not a neutral policy but a form of **structural discrimination**. It singles out a patient group whose clinical need is immediate relief, criminalising the only effective route. Cannabis is uniquely criminalised by route, even though other prescribed medicines carry greater risks and face no such prohibition (see Sections 8.1 and 13).

15.3 Legal vulnerabilities

The measure is vulnerable on multiple grounds:

- **Equality Act 2010**: failure to make reasonable adjustments, indirect discrimination, direct discrimination. (see Section 8.1)
- **Human Rights Act 1998**: disproportionate interference with Articles 8 and 14, potential breach of Article 3. (see Sections 8.2 and 13.2).
- **Public law**: Wednesbury unreasonableness, failure of proportionality, procedural impropriety. (see Sections 10.2 & 10.3).
- **Constitutional principle**: violates the residual liberty principle by layering prohibition within permission. (see Sections 3.6 and 6.3).

15.4 Remedies available

1. **Equality adjustment**: create exemptions where smoking is the only effective route for disabled patients (see Sections 8.1 and 13.3).
2. **Human rights compliance**: align UK practice with Article 8 and 14 obligations by enabling lawful access where clinically justified (see Section 14.3).
3. **Research facilitation**: permit clinical trials of smoked cannabis under licence to generate the evidence base currently suppressed (see Sections 7.3–7.5 and 9 & 10).

4. **Regulatory reform**: introduce proportionate safeguards (dosage guidance, labelling, clinical monitoring) rather than prohibition (see Section 4.3).
5. **Targeted legislative amendment (if required):** revise Regulation 16A(3) to permit clinically justified smoking under controlled conditions, removing the categorical route ban.

15.5 Broader implications

Implementing the remedies above would:

- Enable clinicians to prescribe the most effective route.
- Allow patients to act lawfully, restoring trust in medical relationships.
- Reduce stigma and discrimination against cannabis patients.
- Save resources for police, CPS, and courts.
- Align UK law with international comparators and human rights standards (see Section 14).

15.6 Link to open letter

This briefing should be read alongside the Open Letter of 16 June 2025, which sets out immediate asks for ministers, regulators, and public bodies. The two documents are complementary: the letter frames the political and policy request; this briefing provides the detailed legal and evidential analysis. Taken together, they demonstrate that Regulation 16A(3) requires a co-ordinated cross-government response, extending beyond the specific recommendations in the letter to encompass the remedies identified here.

The Remedy Is Simple

No consultation. No evidence. No equality assessment. A prohibition that criminalises patients and silences clinicians. The remedy is simple: **remove the carve-out, regulate responsibly, and restore fairness.**

Annex A

Table A1: Comparative Drug Harms – UK MCDA Ranking (Nutt et al., 2010)

Source: Nutt, D., King, L.A., & Phillips, L. (2010). Drug harms in the UK: a multicriteria decision analysis. The Lancet, 376(9752), 1558–1565.

This landmark UK study applied a multicriteria decision analysis to 20 substances across 16 harm criteria. Alcohol ranked as the most harmful overall; cannabis sat well below tobacco and alcohol, in the lower tier of harms.

Substance	Overall Harm	Harm to Users	Harm to Others
Alcohol	72	34	38
Heroin	55	34	21
Crack cocaine	54	37	17
Cocaine	27	27	20
Tobacco	26	23	14
Amphetamine	23	23	10
Cannabis	20	20	6
GHB	19	19	6
Benzodiazepines	15	15	7
Ketamine	15	15	7
Methadone	14	13	1
Mephedrone	13	13	0
Butane	11	11	0
Khat	9	9	0
Anabolic steroids	9	9	0
Ecstasy	9	9	0
LSD	7	7	0
Buprenorphine	7	7	0
Mushrooms	6	5	1

Table A2: Comparative Drug Harms – EU MCDA Ranking (van Amsterdam et al., 2015)

Source: van Amsterdam, J., Nutt, D., Phillips, L., & van den Brink, W. (2015). European rating of drug harms. Journal of Psychopharmacology, 29(6), 655–660.

A Europe-wide expert panel applied the same methodology, confirming the UK findings with almost identical results (correlation ≈ 0.99). Again, cannabis was ranked far below tobacco and alcohol, with relatively low harm scores.

Substance	Overall Harm	Harm to Users	Harm to Others
Alcohol	72	34	38
Heroin	55	34	21
Crack cocaine	50	37	13
Cocaine	27	26	1
Tobacco	26	23	3
Amphetamine	23	20	3
Cannabis	20	20	0
Benzodiazepines	15	15	0
Methadone	14	14	0
Ketamine	15	15	0
GHB	19	19	0
Mephedrone	13	13	0
Butane	11	11	0
Anabolic steroids	9	9	0
Ecstasy	9	9	0
LSD	7	7	0
Buprenorphine	7	7	0
Mushrooms	6	6	0
Khat	9	8	1

Annex B - Recent research (& Research gaps)

Since 2018 new studies have partly filled the evidential gap with recent real-world studies that have begun to document how prescribed cannabis is used in practice. Project Twenty21 in the UK, for example, has reported that high-THC flower is among the most frequently prescribed products, with associated improvements in patient-reported quality of life and reductions in concomitant opioid or analgesic use.

In Germany, individual application data show that while most patients use a single route, a minority combine methods, with smoking and vaporisation together being the most common combination.

Although this confirms that some prescribed patients do smoke their cannabis, most often in combination with vaporisation, the dataset did not publish a breakdown of exclusive smoking versus other single-route use, leaving the true prevalence unclear.[1] These findings underline both the presence of inhaled use within lawful prescribing regimes and the evidential gap created by the current prohibition: distinctions between smoking and vaporisation are seldom recorded, long-term outcomes by route remain under-examined, and systematic monitoring has been constrained by the exclusion of smoked CBPMs.

In the UK, the Project Twenty21 dataset is likely to understate smoking because patients are reporting within a framework where combustion of prescribed cannabis remains unlawful. By contrast, the German evidence confirms that smoking does occur within a lawful prescribing regime, but the published analysis does not differentiate exclusive smoking from other single-route use, leaving the prevalence uncertain.

Comparable studies in Canada, the United States and oncology populations internationally suggest a similar picture, with inhalation persisting as a common route. However, in many of these settings the data combine prescribed and self-directed medical use, so they are less precise than the UK and German evidence in distinguishing how prescribed CBPMs are administered. For cultural context, national survey data from Germany show that smoking remains the overwhelmingly dominant mode of cannabis use in the general population, underscoring the gap between clinical reporting practices and wider patterns of use (see prescribed CBPM studies and general population comparators in the references at the end of this section).

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[1] *This omission likely reflects both the small numbers in the dataset and regulatory discouragement of smoking, which can bias what researchers choose to report.*

Annex B: Evidence at a Glance — Routes of Cannabis Administration

The table below summarises the available evidence on how cannabis is used across different settings, distinguishing prescribed CBPM studies from international comparators and general population surveys.

Evidence Tier	Key Sources	Main Findings	Limitations
Prescribed CBPMs (UK & Germany)	Project Twenty21 (Schlag et al. 2022; 2023) Hundertmark et al. 2025	UK: High-THC flower frequently prescribed; improvements in QoL and reduced opioid use. Germany: Some prescribed patients smoke cannabis, often alongside vaporisation.	UK: Smoking likely under-reported due to prohibition. Germany: Prevalence of exclusive smoking not reported.
International medical comparators	Boehnke et al. 2019 (US) Lucas et al. 2019 (Canada) Vinette et al. 2022 (Oncology review)	Inhalation remains common internationally; substitution from opioids reported; oncology patients use multiple routes.	Often combine prescribed and self-directed use, limiting precision.
General population (context only)	Orth et al. 2024 (Germany, national survey)	~92% of past-year cannabis users smoke (often with tobacco).	Not specific to prescribed CBPMs; included for cultural context only.

Table B – Evidence at a glance

Recent Research

- Schlag, A.K., O'Sullivan, S.E., Zafar, R.R. & Nutt, D.J. (2022). Characteristics of people seeking prescribed cannabinoids for the treatment of chronic pain: Evidence from Project Twenty21. *Frontiers in Pain Research*, 3, 891498. https://www.drugscience.org.uk/characteristics-of-people-seeking-prescribed-cannabinoids-for-the-treatment-of-chronic-pain-evidence

  Baseline profile of UK patients prescribed cannabis for chronic pain.

- Schlag, A.K., Robinson, E., Erridge, S., Sessa, B., O'Sullivan, S.E. & Nutt, D.J. (2023). Characteristics of and 3-month health outcomes for people seeking treatment with prescribed cannabis: Real-world evidence from Project Twenty21. *Expert Review of Clinical Pharmacology*, 16(5), 537–548. https://www.drugscience.org.uk/characteristics-of-and-3-month-health-outcomes-for-people-seeking-treatment-with-prescribed-cannabis

Reports both baseline characteristics and 3-month health outcomes for UK patients prescribed cannabis.

- Hundertmark, J., Lintz, K., Dersch, R. & Werse, B. (2025). Individual application patterns of cannabis-based medicinal products: Evidence from patient self-reports. *Forensic Science International*, 354, 111040. https://pubmed.ncbi.nlm.nih.gov/39709741/

  German study showing how prescribed patients use cannabis, including some who smoke (often alongside vaporisation).

International comparators – mixed prescribed/self-directed medical use

- Boehnke, K.F., Scott, J.R., Litinas, E., Sisley, S., Clauw, D.J. & Bohnert, K.M. (2019). Medical cannabis use preferences and decision-making among medical cannabis users with chronic pain. *The Journal of Pain*, 20(11), https://pubmed.ncbi.nlm.nih.gov/31132510/

  US survey of chronic pain patients on preferred routes (smoking, vaping, edibles, oils).

- Lucas, P., et al. (2019). Medical cannabis patterns of use and substitution for opioids and other pharmaceuticals: Results from a cross-sectional survey. *Harm Reduction Journal*, 16, 9. https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-019-0278-6

- *Canadian survey of medical users, focusing on substitution away from opioids and prescription drugs.*

- Vinette, B., et al. (2022). Routes of administration, reasons for use, and approved indications for medical cannabis in oncology: A scoping review. *BMC Cancer*, 22, 942

  https://bmccancer.biomedcentral.com/articles/10.1186/s12885-022-09378-7

  Review of international oncology studies; summarises routes of administration and clinical contexts.

General population comparator (context only)

- Orth, B., et al. (2024). Prevalence of cannabis use modes and use characteristics among past-year cannabis users in Germany: Results of the Epidemiological Survey of Substance Abuse 2021. *International Journal of Environmental Research and Public Health*, 21(1), 19.

  https://di.aerzteblatt.de/int/archive/article/236920

German national survey showing ~92% of past-year users consume cannabis by smoking (usually with tobacco); included for cultural context only, not prescribed CBPM use.

Annex C: Full Distribution List

Home Secretary	Rt Hon. Yvette Cooper MP
Health & Social Care Secretary	Rt Hon. Wes Streeting MP
Transport Secretary	Rt Hon. Heidi Alexander MP
Justice Secretary	Rt Hon. Shabana Mahmood KC MP
Work & Pensions Secretary	Rt Hon. Liz Kendall MP
Department for Education	Minister for Women and Equalities
Cabinet Office	Rt Hon. Nick Thomas-Symonds MP
Metropolitan Police Commissioner	Sir Mark Rowley QPM
Mayor of London	Sadiq Khan
Chief Executive, NHS England	Sir James Mackey

Annex D – Impact Assessment and Parliamentary Procedure Review

For consideration alongside the briefing “Discrimination by Design” – (Submitted to the Home Office and other Government Departments on 18 Sept 2025) and Supplementary Annex E to that analysis, to the Call for evidence to support ACMD's review of changes to legislation on the use of cannabis-based products for medicinal purposes (CBPMs). This analysis is submitted following advice from the Home Office, Drug and Alcohol Unit.

Purpose and Scope

1. This Annex updates the analysis originally presented in Discrimination by Design (September 2025) and in correspondence issued to relevant departments since June 2025. It has been prepared for cross-government and parliamentary consideration, recognising that responsibility for the 2018 legislative package was divided as follows:

    - **Home Office** – lead department under the Misuse of Drugs Act 1971 and sponsor of both instruments;
    - **Department of Health and Social Care (DHSC)** – clinical governance, prescribing practice and patient safety;
    - **Department for Transport (DfT)** – drug-driving and impairment-testing policy;
    - **Ministry of Justice (MoJ)** – criminal-justice, prosecution and sentencing impacts;
    - **Cabinet Office / Equality Hub (on behalf of the Minister for Women and Equalities)** – cross-government oversight of compliance with the Equality Act 2010, including the Public Sector Equality Duty (PSED);
    - Equality and Human Rights Commission (EHRC) – independent statutory regulator under the Equality Act 2010, responsible for monitoring and enforcing the PSED across public authorities.

2. Its purpose is to assess whether the available Impact Assessment material associated with the 2018 legislative package – comprising the draft Misuse of Drugs Act 1971 (Amendment) (No. 2) Order 2018 and the accompanying Misuse of Drugs (Amendments) (Cannabis-based Products for Medicinal Use) Regulations 2018 (SI 2018/1055) – met the procedural and substantive standards required under the Misuse of Drugs Act 1971 and under government policy for secondary legislation.

3. The Annex does not introduce new policy questions. Its function is to collate and update existing evidence and to correct the record where earlier assessments appear incomplete or inconsistent with the published legislative framework.

Background

4. The 2018 Regulations introduced “cannabis-based products for medicinal use in humans” (CBPMs) as a new sub-category within Schedule 2 of the Misuse of Drugs Regulations 2001 (MDR 2001).

5. Current research suggests that the 2018 policy change was implemented through two inter-linked statutory instruments:
   - **The Misuse of Drugs Act 1971 (Amendment) (No. 2) Order 2018 (draft affirmative**), which re-scheduled cannabis-based medicinal products from Schedule 1 to Schedule 2 of the Act and was debated and approved by both Houses on 31 October 2018; and
   - **The Misuse of Drugs (Amendments) (Cannabis-based Products for Medicinal Use) Regulations 2018 (SI 2018/1055),** laid under the negative procedure, which inserted Regulation 16A into the 2001 Regulations and introduced the prohibition on smoking.
   - This two-stage approach enabled parliamentary debate on the principle of rescheduling but not on the operational restrictions subsequently applied through the Regulations.
6. Regulation 4 of SI 2018/1055 inserted a new Regulation 16A, imposing additional controls beyond those ordinarily applicable to Schedule 2 drugs. Paragraph (3) of that regulation states: - “Nothing in these Regulations shall authorise the smoking of cannabis, or the supply of cannabis for the purpose of being smoked.”

7. **The effect is that patients prescribed CBPMs are excluded from the ordinary protections provided under Regulations 6, 10 and 16 of the MDR 2001, which would otherwise render possession, administration and supply lawful when carried out in accordance with a practitioner’s prescription or direction.**

8. No equivalent limitation applies to any other controlled drug. This creates a unique legal and clinical anomaly in which a clinically recognised route of administration – inhalation by combustion – remains criminalised even when prescribed for therapeutic use.

Impact Assessment (IA) – Procedural and Substantive Review

9. The Home Office has stated that an Impact Assessment was prepared in connection with the 2018 Regulations, and a short document (UKIA 20180129) later appeared on the legislation.gov.uk “More Resources” tab. However, the status and timing of that assessment remain unclear, and it does not appear to have been subject to the ordinary Regulatory Policy Committee process.

10. Although a brief ‘de minimis’ Impact Assessment (UKIA 20180129) now appears online for SI 2018/1055, it was not referenced in the Explanatory Memorandum and there is no public record of RPC clearance. The parallel affirmative Order for

SI2018/1536, carried none. While such omissions have precedents (for example, the 2012 and 2015 Misuse of Drugs (Amendment) Regulations), scrutiny committees have repeatedly criticised them as contrary to the spirit of the Better Regulation Framework and to good legislative practice.

11. By contrast, the Misuse of Drugs Act and Cabinet Office Guidance require that any legislative proposal likely to alter the conditions of lawful possession or supply of a controlled drug be supported by an IA prepared to the same evidential standard as for primary legislation. The 2018 package therefore appears to have been prepared to a lower procedural standard than the parent Act demands.

12. The IA's focus was almost exclusively on anticipated administrative and enforcement costs. It did not quantify or even acknowledge potential equality, clinical or human-rights impacts arising from the criminalisation of a route of administration that could otherwise be prescribed and overseen by clinicians. Differential treatment of disabled patients, the foreseeable enforcement burden on police and courts where patients cannot evidence lawful possession in practicable form, the chilling effect on clinicians' willingness to prescribe CBPMs, and the barrier to research and clinical trials are all created by the prohibition on smoking.

13. There is no evidence that the IA was updated after prescribing commenced in November 2018, despite mounting clinical evidence of divergent patient outcomes by route of administration. Nor is there evidence of any post-implementation review addressing equality or patient impacts, contrary to the Government's own post-legislative scrutiny obligations.

14. While government guidance has cited vaporisation as a clinically acceptable and safer substitute for smoking, available pharmacokinetic and real-world data do not demonstrate functional equivalence for all patient groups. In particular, conditions requiring immediate symptom control – such as severe pain, spasticity or motor instability – show faster, more reliable and controllable relief from smoked administration. The absence of any formal evaluation of these sub-group outcomes further underscores the deficiency of the 2018 Impact Assessment.

Choice of Parliamentary Procedure

15. The 2018 policy package comprised the Misuse of Drugs Act 1971 (Amendment) (No. 2) Order 2018 (draft affirmative) and the Misuse of Drugs (Amendments) (Cannabis-based Products for Medicinal Use) Regulations 2018 (SI 2018/1055) (negative). Both were laid concurrently and debated in the Commons and Lords on 31 October 2018.

16. While the Order received full parliamentary debate, the accompanying Regulations – which introduced Regulation 16A and the prohibition on smoking – were treated as consequential and were not subject to equivalent scrutiny or amendment. **This division between the affirmative and negative instruments meant that**

Parliament approved the principle of medical access without ever considering the restrictive details that narrowed it.

17. This hybrid approach blurred the boundary between measures requiring affirmative approval and those eligible for negative procedure. Comparable scheduling exercises (such as the gabapentin and pregabalin re-classification in 2018–19) followed the orthodox two-step route with both affirmative and negative instruments clearly delineated whilst their procedural paths involved public consultation and transparent impact assessment; (See main briefing Sections 6 & Section 7) in the CBPM case, the substantive prohibitions were introduced only through the negative Regulations, escaping parliamentary scrutiny or amendment. - ***Editorial update highlighted to broaden explanation***

Evaluation of Equality and Patient Impacts

18. No evidence has been identified that the Home Office or DHSC undertook a formal Equality Impact Assessment (EqIA) prior to or following the 2018 amendment. Nor is there evidence that patient-impact considerations were referred to the Office for Life Sciences, NICE or NHS England for evaluation.

19. No record has been identified of consultation with the Equality and Human Rights Commission (EHRC), the statutory regulator under the Equality Act 2010, in relation to the Public Sector Equality Duty (PSED) implications of the 2018 amendment.

20. **Given that the affected population consists exclusively of patients with chronic or disabling medical conditions, and that the policy directly limits their lawful routes of administration, the absence of equality analysis represents a significant procedural omission. It also risks non-compliance with the Government's obligations under the Equality Act 2010 (s.149), Article 14 ECHR (non-discrimination in enjoyment of Convention rights), and Articles 25–26 UN CRPD (equal access to health care and rehabilitation services).**

21. The clinical evidence base recognises multiple effective routes of cannabinoid administration – oral, sublingual, vaporised and smoked. However, only the first three are legally authorised in the UK: Regulation 16A(3) expressly prohibits smoking. This creates a disjunction between clinically recognised and legally authorised routes of administration, which should have been central to any equality or patient-impact assessment. **A lawful EqIA would have been expected to consider alternative policy options (such as a limited medical exemption for smoking under clinical supervision) rather than an absolute prohibition. The absence of such consideration deprived Ministers and Parliament of the opportunity to weigh proportionality or explore mitigations.**

22. The published Impact Assessment (UKIA 20180129, para 70) stated that "prohibiting smoking as a mode of administration will help police officers differentiate between

legitimate and illicit cannabis use." No equivalent analysis was undertaken of how such a prohibition would affect patients whose clinically effective route of administration is by inhalation. The only assessed impact concerned enforcement convenience, not patient safety or equality**. This omission further demonstrates that the 2018 Impact Assessment failed to evaluate foreseeable clinical and human-rights consequences arising from Regulation 16A(3).**

23. The same Impact Assessment suggested that prohibiting smoking would produce "minor savings to police and enforcement agencies" by simplifying enforcement and reducing time spent verifying prescriptions. In practice, cannabis-related offences continue to represent a high proportion of drug arrests and prosecutions across the UK, consuming substantial police and court resources. Enforcement activity short of prosecution – including stop-and-searches, seizures, testing and evidential review – constitutes a significant operational burden. By maintaining the criminalisation of smoking even for prescribed patients, Regulation 16A(3) perpetuates rather than reduces this drain on resources, undermining the Impact Assessment's own cost-saving rationale.

Oversight and Cross-Government Responsibilities

24. Responsibility for the 2018 amendment was primarily held by the Home Office, as sponsor department under the Misuse of Drugs Act 1971. However, the change had direct implications for DHSC (clinical governance, prescribing practice, patient safety), DfT (drug-driving and impairment testing), MoJ (criminal-justice and sentencing impacts) and the Cabinet Office / Equality Hub (cross-government equality and legislative standards).

25. It is not clear whether the Impact Assessment Clearing Panel (IACP) or Regulatory Policy Committee (RPC) were consulted on the IA, or whether cross-departmental clearance was obtained before laying the instrument. There appears to be no public record of joint sign-off by DHSC or the Cabinet Office.

Post-Implementation Considerations

26. Since 2018 there has been no systematic evaluation of clinical or equality outcomes arising from the current regime. Emerging real-world data from UK registries indicate material differences in treatment effectiveness, adherence and patient-reported outcomes between oral and inhaled routes, but these findings have not been considered within government review processes.

27. Because Regulation 16A(3) prohibits smoking as a lawful route of administration, no clinical, safety or outcome data on smoked CBPMs can lawfully be collected, creating a structural evidence gap that prevents comprehensive evaluation of inhalation-based treatment. Failure to undertake such evaluation continues to undermine the evidential basis of Regulation 16A(3).

28. **This creates a self-reinforcing "policy trap," previously identified in Discrimination by Design, in which the absence of lawful data is used to justify maintaining the very prohibition that prevents its collection. By excluding smoking from lawful clinical use, Regulation 16A(3) ensures that no empirical evidence on its safety, efficacy or patient outcomes can emerge, while policy-makers continue to cite the resulting evidential gap as grounds for withholding reform. The regulation thus both causes and perpetuates the absence of evidence needed to evaluate its proportionality, locking patients and clinicians into a closed evidential circuit that cannot self-correct without legislative change.**

29. In contrast, comparable post-implementation reviews for other Schedule 2 drugs—such as morphine, fentanyl, or gabapentin following rescheduling—have routinely assessed prescribing patterns, enforcement consequences, and equality implications. No such structured review has yet been undertaken for CBPMs, despite repeated ministerial statements describing the 2018 reforms as "interim."

Summary and Next Steps

30. This Annex concludes that it remains unclear whether the 2018 legislative package was supported by any formally approved, full-scope Impact Assessment meeting the evidential standards ordinarily required under the Misuse of Drugs Act 1971. Key deficiencies include:
    - failure to assess equality, patient or clinical impacts;
    - preparation of any available IA to a lower standard than required;
    - use of the negative procedure despite substantive legal change; and
    - absence of cross-departmental oversight or post-implementation review.

31. In view of these findings, it is recommended that the Home Office, DHSC and other relevant departments review the adequacy of the 2018 Impact Assessment and its compliance with the Equality Act 2010 and Better Regulation Framework. This review could be undertaken either jointly by departments or under the oversight of the Cabinet Office to ensure consistency with cross-government standards.

32. The purpose of these recommendations is not prescriptive but collaborative: to assist government in identifying proportionate, lawful and evidence-based options for addressing the regulatory and equality gaps highlighted above. The intention is to support rather than criticise, recognising that the 2018 reforms were implemented under significant time pressure and evolving clinical evidence.

33. I would of course welcome an opportunity to engage constructively with officials across departments to clarify factual points, share patient-reported data, and contribute to any further review or consultation process the Government may choose

to initiate. The accompanying cover note identifies the specific questions relevant to departmental responsibilities and provides contact details for follow-up discussion. – [Editors Note: The reference to the cover note relates to emails issued to all parts of Government with questions to answer under Annex E]

References

- Misuse of Drugs Act 1971
- Misuse of Drugs Regulations 2001 (as amended by SI 2018/1055)
- UK Impact Assessment (UKIA 20180129)
- Cabinet Office Better Regulation Framework Guidance (2023 update)
- Equality Act 2010 s.149
- Human Rights Act 1998 (Article 14 ECHR)
- UN Convention on the Rights of Persons with Disabilities (Articles 25–26)
- Statutory Instruments Act 1946
- House of Lords Companion to the Standing Orders (2024 edition)

Annex E – Departmental and Cross-Government Questions

(October 2025 – for submission alongside the briefing "Discrimination by Design" – Submitted to the Home Office and other Government Departments on 18 Sept 2025) and Supplementary Annex E to that analysis, to the Call for evidence to support ACMD's review of changes to legislation on the use of cannabis-based products for medicinal purposes (CBPMs). This analysis is submitted following advice from the Home Office, Drug and Alcohol Unit.

For Consideration – drawn from real patient experiences: A medical cannabis patient is in an enclosed public space – covered market, pub, cinema, or even a shop, hospital or police station. The patient uses their prescribed medication to manage acute symptoms, in the same way that an asthma patient uses their inhaler.

Does the patient's need to medicate with inhaled cannabis override the venue's right to prohibit vaping or smoking on the premises?

This scenario highlights the practical collision between disability accommodation and blanket vaping or smoking bans — a gap no current guidance addresses."

Purpose and Scope

This annex sets out the current set of departmental and cross-government questions arising from the collective analysis presented across Discrimination by Design and Annex D – Review of Impact Assessment and Parliamentary Procedure.

The questions below are drawn directly from the issues identified within those analyses and are addressed to the relevant departments and public bodies according to their statutory responsibilities.

They are intended to assist in clarifying evidential, procedural, and equality-law matters relating to Regulation 16A(3) of the Misuse of Drugs Regulations 2001, as inserted by the Misuse of Drugs (Amendments) (Cannabis-Based Products for Medicinal Use) Regulations 2018 (SI 2018 No. 1055 and SI 2018 No 1356).

Questions for the Home Office

1. **Competence and responsibility**
   How does the Home Office reconcile its statement that the Department of Health and Social Care holds medicines-policy responsibility with the fact that the Misuse of Drugs Regulations 2001 (as amended by SIs 2018 Nos. 1055 and 1356) remain within Home Office legislative competence and enforcement oversight?

2. **ACMD advice and its scope**
   Will the Home Office publish, or make available to Parliament, the full Advisory Council on the Misuse of Drugs (ACMD) advice relied upon to justify continued prohibition of smoking as a route of administration, including its date, evidence base, and any equality- or clinical-impact assessments considered? In addition, what was the intended scope and status of that advice, and to what extent does the Department consider it determinative of, or constrained by, the limitations imposed under Regulation 16A(3)?

3. **Evidential basis for prohibition**
   What evidence or comparative analysis supports the assertion that "smoking … is not authorised or supported as a method for delivering any medicine," and how has the Department distinguished this absolute prohibition from the regulatory treatment of other controlled medicines with recognised risks, whether respiratory, neurological, cardiovascular or otherwise?

4. **Regulatory inconsistency**
   Does the Department accept that Regulation 16A(3) prevents prescribers from lawfully authorising administration by combustion, rendering the advice to "consult your GP about lawful administration" ineffective in practice? If so, what steps are planned to address this inconsistency?

5. **Equality and disability impact**
   What analysis or due-regard assessment did the Department undertake at the time of the 2018 amendments, and what record exists of any Equality Impact Assessment or Public Sector Equality Duty consideration?

6. **Parliamentary procedure**
   Has the Department reviewed whether the 2018 decision to apply the negative procedure complied with Cabinet Office guidance on scrutiny of secondary legislation with equality implications?

7. **Interaction with other provisions**
   What assessment has been made of the interaction between Regulation 16A(3) and Regulations 6, 10 and 16 of the Misuse of Drugs Regulations 2001, which otherwise authorise lawful possession and use under a practitioner's prescription?

8. **Data and monitoring**
   What data is collected by the Home Office or its agencies on stops, searches or seizures involving patients prescribed CBPMs, and how is this used to monitor compliance with the Equality Act 2010?

9. **Operational coordination**
   What arrangements exist with police forces and the CPS to ensure that enforcement practice does not conflict with lawful medical use of CBPMs or discriminate against disabled patients?
10. **Proportionality**
    Has the Department assessed whether restrictions under Regulation 16A(3) create a disproportionate impact on disabled or chronically ill patients, and what evidence supports any contrary conclusion?

11. **Device standards, certification and legal classification**
    What guidance or technical standards currently apply to vaporising devices used for lawful administration of CBPMs, and which authority or body holds responsibility for their certification or approval?

    What assessment has been made of whether temperature control or device configuration affects the point at which use of such a device may constitute a statutory offence under Regulation 16A(3)?

12. **Externally heated devices**
    Certain vaporising devices employ an **externally applied heat source** (for example, torch-heated or flame-heated glass or metal chambers) to achieve vaporisation without direct combustion. How does the Home Office classify such externally heated devices for the purposes of Regulation 16A(3) and, in cases where such a device unintentionally overheats or partially combusts material during lawful medical use, does this alter the patient's legal status or create criminal liability? What evidential or policy basis governs that distinction?

13. **Equality of access and cost**
    Has the Department considered whether mandating or restricting specific devices imposes costs that may affect equality of access, and, if so, what mitigation is proposed?

14. **Interim guidance**
    Pending full review of Regulation 16A(3), has the Home Office considered issuing interim guidance or discretionary arrangements to mitigate disproportionate impacts on protected groups under the Equality Act 2010?

15. **Mixtures with other herbs, flavouring agents or tobacco**
    How does the Department interpret Regulation 16A(3) in relation to **medical cannabis** vaped in combination with other herbs, flavouring agents or tobacco, and on what legal or evidential basis has that interpretation been formed?

16. **Liquid or semi-solid mixtures**
    How are liquid or semi-solid preparations containing cannabis with other compounds (for example, terpenes, propylene glycol or glycerin) classified for enforcement purposes?

17. **Guidance to enforcement bodies**
    What written guidance has been issued to police forces, the CPS or clinicians to help distinguish between these mixed-substance cases in practice?

18. **Point of criminal liability (preparatory acts)**
    In scenarios where a lawfully prescribed patient prepares combinations of cannabis with other substances for vaping, at what stage does the Department consider any criminal offence to be made out? What statutory provisions and evidential standards does the Department rely upon for that view?

19. **Edibles and reuse**
    What is the Department's position on the lawfulness of a patient preparing edibles from their lawfully prescribed CBPM (e.g. whole-flower) for their own medical use where no smoking occurs and the preparation is undertaken to follow clinical direction for non-smoked administration?

    Given that decarboxylation occurs during vaporisation, what is the legal status of a patient reusing vaporised cannabis residue from their prescribed CBPM to prepare edibles for their own medical use? Does the Department regard such reuse as a continuation of lawful medical use or as a separate act engaging criminal liability, and on what statutory and policy basis?

Cross-Government Consistency

E 19 addresses the boundaries of lawful use and liability within the current regulatory framework.

E 20 then addresses the related issue of cross-government consistency. Under the Road Traffic Act 1988 and DVLA medical standards administered by the Department for Transport, impairment-based safeguards already protect prescribed patients who may exceed analytical thresholds without being impaired. The continued Home Office prohibition on smoked administration prevents those statutory safeguards from operating consistently for CBPM patients. Clarification is therefore sought on the legal and evidential basis for maintaining that departure from the impairment-based model applied to all other prescribed controlled medicines.

20. Impairment-based safeguards and cross-government consistency

The Department for Transport's impairment-based framework under the Road Traffic Act 1988 and DVLA medical fitness-to-drive standards already provides a statutory safeguard for prescribed patients, recognising that therapeutic use may result in detectable drug levels above analytical thresholds without impairment.
Why does the Home Office continue to maintain a route-based criminal prohibition that prevents this statutory safeguard from operating consistently for prescribed CBPM patients?

What clinical or scientific evidence supports maintaining that departure from the impairment-based model applied across all other prescribed controlled medicines?

Please also set out the medical and legal justification for this continued exceptionalism, (as set out in Section 7 of Discrimination by Design), and indicate which statutory or evidential tests were applied to support it.

Questions for DHSC

21. How has DHSC assessed the clinical-governance implications of Regulation 16A(3) for patients prescribed CBPMs whose optimal route of administration remains criminalised?

22. What equality and disability-impact analysis has DHSC undertaken regarding patient access, adherence and continuity of care under current restrictions?

23. How does DHSC ensure that prescribing guidance for clinicians is consistent with the statutory limitations imposed by Regulation 16A(3)?

24. What systems are in place to collect and analyse data on patient safety, treatment efficacy and equality impacts where legal or regulatory restrictions on route of administration may limit a patient's ability to obtain clinically equivalent benefit from their prescribed medication?

25. How does DHSC coordinate with NHS England and the Home Office to address policy or evidence gaps arising from the absence of a lawful route of administration?

26. Does DHSC intend to review or refresh its published guidance in light of the equality-law and clinical-safety issues identified?

27. Interim patient-safety and equality measures - In light of the evidential and equality gaps identified in Discrimination by Design and its associated annexes, what interim measures, if any, has DHSC considered to protect patient safety and equality of access under the Equality Act 2010 pending full resolution of the legal and regulatory issues surrounding Regulation 16A(3)?—

Questions for the Ministry of Justice

28. How does the Ministry assess the compatibility of Regulation 16A(3) with the Equality Act 2010 and the Human Rights Act 1998, particularly in relation to proportionality and non-discrimination?

29. What assessment has been made of potential indirect discrimination against disabled patients under section 19 of the Equality Act, and how is that risk mitigated?

30. How does the Ministry interpret the extent to which the Public Sector Equality Duty was discharged during the making of SI 2018 No. 1055, and what lessons have been learned for future secondary legislation?

31. What processes are in place to ensure that departments record and retain the evidence base underpinning equality-law compliance when drafting statutory instruments of comparable significance?

32. Should a cross-government review determine that Regulation 16A(3) operates incompatibly with equality or human-rights obligations, what legal or procedural mechanisms would the Ministry expect to be used to amend or revoke it?

33. How does the Ministry oversee inter-departmental coordination on equality and human-rights matters arising from legislation administered by other departments?

34. What guidance does the Ministry provide to ensure that courts and tribunals interpret conflicting statutory provisions — such as between Regulation 16A(3) and Regulations 6, 10 and 16 — consistently with human-rights and equality principles?

35. Will the Ministry consider whether current oversight mechanisms for statutory instruments provide adequate protection against inadvertent breaches of equality or human-rights law?

Questions for the Equality Hub / DfE

36. How does the Equality Hub monitor compliance with the Public Sector Equality Duty in relation to secondary legislation such as SI 2018 No. 1055, which has significant disability and health implications?

37. Given that the 2018 Instrument was subject to both negative and affirmative procedures in related contexts (for instance, the upgrading of gabapentin and pregabalin to Schedule 3 under the affirmative procedure), what analysis has been made of whether the downgrading of cannabis-based products from Schedule 1 to Schedule 2 warranted the higher level of scrutiny, and why the lesser procedure was adopted in this case?

38. What guidance does the Equality Hub issue to ensure departments maintain adequate records of PSED considerations during the preparation of statutory instruments?

39. How does the Hub coordinate with the Cabinet Office and the Government Equalities Office to ensure consistency of equality-law compliance across departments when regulatory change has cross-cutting disability impacts?

40. What mechanisms exist for the Hub to review the cumulative equality impact of secondary legislation that, while lawful individually, may together create systemic disadvantage for disabled people?

41. **Cross-government interim arrangements** - Given the evidential gaps set out in Discrimination by Design and its associated annexes, what interim or holding arrangements does government consider appropriate to protect the rights and interests of disabled patients under the Equality Act 2010 while these issues remain under review? If no such arrangements are considered necessary, what is the legal and equality-law rationale for that position?

Questions for NHS England

42. How does NHS England ensure that patients prescribed CBPMs receive clear, accurate information about the lawful routes of administration available to them?

43. What guidance has been issued to prescribers and dispensers to avoid contradiction between clinical advice and the legal restrictions imposed by Regulation 16A(3)?

44. How does NHS England monitor the impact of Regulation 16A(3) on patient adherence, continuity of care and clinical outcomes, and how is this information used to inform commissioning or policy advice?

45. Are there arrangements to collect or publish data on patient reports of enforcement or access difficulties linked to this regulation?

46. How is NHS England working with DHSC and the Home Office to clarify operational interfaces between clinical and legal frameworks, and to ensure that equality considerations are integrated into those discussions?

47. What processes exist for NHS England to escalate equality or patient-safety concerns to DHSC or other departments where regulatory barriers are impeding clinical care?

48. **Interim patient-protection arrangements** - Given the evidential and equality gaps identified in Discrimination by Design and its associated annexes, what interim or contingency measures has NHS England considered to protect patient safety and equality of access under the Equality Act 2010 while these issues remain unresolved?

Questions for the Metropolitan Police Service

49. What operational guidance exists to help officers differentiate between prescribed and non-prescribed cannabis-based products?

50. How are officers trained to recognise and respond appropriately to disabled patients whose symptoms may be misinterpreted as impairment?

51. Does the Metropolitan Police Service collect data on stops, searches or seizures involving patients prescribed CBPMs, and how is that data used to evaluate proportionality?

52. What operational guidance is provided to help officers distinguish between lawful prescribed use of cannabis-based medicines by vaporisation and unlawful recreational use, given that the two may appear identical in practice?

53. How does the Metropolitan Police Service determine the evidential threshold for enforcement where prescribed cannabis may have been mixed with tobacco, herbal additives or other non-controlled substances, or where a vaporiser requires application of an external heat source that may lead to partial combustion?

54. How does the Service monitor compliance with its equality duties in relation to such enforcement activity?

55. What liaison mechanisms exist between the Met and the Home Office to review enforcement impacts arising from Regulation 16A(3)?

56. What arrangements exist for officers to seek expert or medical clarification before seizure or arrest in cases involving patients prescribed CBPMs?

57. How does the Service ensure that its guidance and training remain consistent with evolving Home Office policy and the Equality Act 2010?

Questions for MOPAC

58. How does MOPAC monitor the Metropolitan Police Service's compliance with the Public Sector Equality Duty in relation to drug enforcement?

59. What analysis has MOPAC undertaken of enforcement actions involving patients prescribed CBPMs, and what trends have been identified?

60. **Oversight of enforcement guidance** - What assurance has MOPAC sought or received from the Metropolitan Police Service regarding the adequacy of operational guidance for differentiating lawful prescribed use of cannabis-based products by vaporisation from unlawful use?

61. **Monitoring fringe-case outcomes** - Does MOPAC review or track complaints, seizures or arrests arising from such cases, and what equality or proportionality issues have been identified?

62. How does MOPAC work with the Home Office and Metropolitan Police to identify systemic equality risks arising from Regulation 16A(3)?

63. Will MOPAC consider commissioning independent review or community scrutiny of these issues within its oversight framework?

64. Disability and equality considerations - How will MOPAC ensure that the review of enforcement practices and disproportionality in drug-related policing commissioned by the Mayor's Office fully incorporates the disability and equality considerations highlighted across the Discrimination by Design briefing and its related annexes?

65. What mechanisms exist for MOPAC to capture and respond to complaints or evidence of disproportionate impact on disabled patients in the application of drug laws?

For Consideration – returning to real patient experiences: *A further scenario, drawn from multiple patient accounts, illustrates how the current prohibition can force an impossible choice.*

Not all medical cannabis patients live in the safest of neighbourhoods. Regardless of whether they are locally known to be vulnerable and obliged by law to carry their prescription in its original packaging, they may feel unsafe to so. Consequently they may carry some of their pre ground medical cannabis prescription, wrapped in a paper cone – simply for ease of refilling the vape chamber for their lawful prescription.

Whilst out, they feel the onset of acute symptoms such as tremors, functional ticks, non epileptic seizures or a range of other symptoms as a result of which they become unable to hold or operate their vaporiser.

Should they knowingly commit a statutory offence by using the part of their prescription held in a cone by smoking? Alternatively, should they continue to allow their symptoms to escalate, knowing that this may potentially place either them or members of the public at risk and require an emergency response?

If such a patient were subsequently prosecuted for the statutory offence, what would be the police and CPS justification that this was in the public interest?

Summary and Next Steps

The questions above collectively address statutory interpretation, equality-law compliance, evidential adequacy, operational guidance and accountability for the administration of Regulation 16A(3) as set out in the Briefing titled Discrimination by Design alongside the supplementary Annexes D and E.

They are circulated to assist departments and agencies in clarifying the current position and identifying any required corrective or interim measures.

A fully updated and integrated v2.0 of this briefing will be released once the emerging online platform is fully functional. It's purpose will be to support wider awareness and informed discussion of this important cross-government matter.

Annex F – Freedom of Information Requests to the Home Office and the Department for Health and Social Care were submitted after the closing date for the ACMD Call for Evidence.

They carry implications for ongoing analysis relating to issues arising from this analysis.

Annex F – FOI Requests to Home Office and DHSC

Annex F is included for transparency and as a reference point to establish the sequence of events that both preceded the laying of Statutory Instruments 2018/1055 and 1356 and the effect and impact of the Regulations since that time. Given the respective statutory obligations of the Home Office and the DHSC raise similar but different questions for each Department as defined by those statutory obligations. Both requests were sent to the Home Office and DHSC respectively on 27/10/2025 by email. Responses to the questions raised will be included in future iterations of Discrimination by Design. The FOI requests are set out on separate pages in order to clearly distinguish them from this explanatory paragraph

Home Office – Freedom of Information Request

Dear Home Secretary and Home Office FOI Team,

Thank you for your continued engagement on this subject. I am submitting the attached Freedom of Information request concerning the equality and impact assessments undertaken during the drafting of the **2018 Misuse of Drugs Regulations**. My purpose is to assist in ensuring that the evidential record around **Regulation 16A(3)** remains complete, transparent, and aligned with the Home Office's duties under the **Equality Act 2010**.

I recognise the statutory 20-working-day timeframe and appreciate the effort required to collate and review historical material. Please find the detailed questions set out below, seeking information held by the Home Office relating to the development, implementation and subsequent consideration of Regulation 16A(3) of the Misuse of Drugs Regulations 2001, as inserted by S.I. 2018 Nos. 1055 and 1056. Note change log correction.

Whilst some of these questions may have been raised previously in outline, I am now restating them formally under the Freedom of Information Act 2000 to ensure that any recorded information identified or considered in response is handled in accordance with the Act's provisions and timescales.

This request falls into three categories:

A. Development and Laying of Regulation 16A(3)

(1 January – 30 November 2018)

1. All correspondence, policy submissions, working drafts, clearance notes or impact-assessment material created or received by the Department between **1 January 2018 and 30 November 2018** that were taken into account in shaping, clearing or laying Regulation 16A(3).
2. Any legal advice or analysis obtained or considered within that period concerning the statutory powers relied upon, the wording of Regulation 16A(3), or its interaction with clinical or equality duties.
3. Any equality-screening, equality-impact or other assessment material (including drafts or internal sign-off forms) used in informing ministerial decision-making at the time of laying.

B. Post-implementation Follow-up

(from implementation of the 2018 Regulations up to the scoping of the recent call for evidence, which closed on 17 October 2025)

4. Any departmental or ministerial correspondence, briefing or review addressing Regulation 16A(3) or its practical effects after implementation and **before** the point at which the Home Office call-for-evidence review on medicinal cannabis was scoped, defined or commissioned.

5. Any record of ministerial comments, commitments or instructions to revisit the 2018 framework and the Department's follow-up actions in response.

C. Scoping and Definition of the Call for Evidence

6. Please confirm whether the review of cannabis-based products for medicinal use now being completed by the Advisory Council on the Misuse of Drugs (ACMD) was commissioned under the Council's **statutory advisory function** in the Misuse of Drugs Act 1971, or whether it was established through **a competitive or commercial process**.

7. If the review was undertaken under a competitive or commercial arrangement, please provide:
   (a) the terms of reference, scope and specification issued;
   (b) any advertisement, invitation-to-tender or call for proposals; and
   (c) any record of award, including evaluation criteria or scoring summaries.

8. If the review was initiated under the ACMD's statutory advisory function, please provide copies of any **formal request, direction or commissioning letter** from the Home Office to the ACMD setting out the objectives, scope and expected outputs of the review.

9. **In the event that the review was conducted under a contract award, and given that any such award is now complete as are the evidence-gathering phases, please confirm whether any relevant information is being withheld on commercial-confidentiality grounds and the reasons for doing so.**

This request forms part of the ongoing correspondence already acknowledged by the Department, including the **open letter of June 2025, *Discrimination by Design* (September 2025), and Supplementary Annexes D and E (October 2025),** together with my formal submission of this analysis to the Home Office call for evidence, which closed on 17 October 2025.

I appreciate that officials must be able to provide frank advice to Ministers without fear of premature disclosure. However, the information sought here concerns work completed and implemented in 2018 and subsequent follow-up **actions up to and including the period in which the Home Office issued the requirement for the now-concluded call for evidence.**

Given the passage of time and the closure of the public evidence-gathering process, the balance of the public interest now lies firmly in transparency over any pre-existing policy rationale and equality considerations rather than preservation of Government's need for deliberative space. Accordingly, any reliance on section 35(1)(a) or related exemptions should be accompanied by the Department's full public-interest test.

Please confirm receipt of this request and respond within twenty working days as required by the Act.

Yours faithfully

Pete Lindsay

DHSC – Freedom of Information Request

Subject: Freedom of Information Request – Clinical, Regulatory and Equality Evidence Relating to Regulation 16A(3) of the Misuse of Drugs Regulations 2001

Dear Health Secretary and DHSC FOI Team,

Thank you for your continued engagement on this subject. I am submitting the attached Freedom of Information request concerning the equality and impact assessments undertaken during the drafting of the **2018 Misuse of Drugs Regulations**. My purpose is to assist in ensuring that the evidential record around **Regulation 16A(3)** remains complete, transparent, and aligned with the Home Office's duties under the **Equality Act 2010**.

I recognise the statutory 20-working-day timeframe and appreciate the effort required to collate and review historical material. Please find the detailed questions set out below, seeking information held by the Home Office relating to the development, implementation and subsequent consideration of Regulation 16A(3) of the Misuse of Drugs Regulations 2001, as inserted by S.I. 2018 Nos. 1055 and 1056. Note change log correction.

Whilst some of these questions may have been raised previously in outline, I am now restating them formally under the Freedom of Information Act 2000 to ensure that any recorded information identified or considered in response is handled in accordance with the Act's provisions and timescales.

This request falls into three categories:

A. Development and Laying of Regulation 16A(3)

(1 January – 30 November 2018)

1. All correspondence, policy submissions, working drafts, clearance notes or impact-assessment material created or received by the Department between **1 January 2018 and 30 November 2018** that were taken into account in shaping, clearing or agreeing Regulation 16A(3) or any related clinical-governance guidance.
2. Any legal advice or analysis obtained or considered within that period concerning the Department's statutory and clinical responsibilities in relation to cannabis-based products for medicinal use, and the equality or patient-safety implications of prohibiting smoked administration.
3. Any equality-screening, equality-impact or other assessment material (including drafts or internal sign-off forms) used in informing departmental or ministerial decision-making during that period.

B. Post-implementation Follow-up

(from implementation of the 2018 Regulations up to the scoping of the Home Office-led call for evidence, which closed on 17 October 2025)

4. Any departmental or ministerial correspondence, briefing or review addressing Regulation 16A(3) or its clinical, prescribing or equality effects after implementation and **before** the point at which the Home Office-led call-for-evidence review on medicinal cannabis was scoped, defined or commissioned.
5. Any record of ministerial comments, commitments or instructions to revisit the 2018 framework and the Department's follow-up actions in response.

C. Scoping and Definition of the Home Office-led Call for Evidence

6. Please confirm what role DHSC has played in the **scoping and definition** of the Home Office-led review of cannabis-based products for medicinal use now being completed by the Advisory Council on the Misuse of Drugs (ACMD).
7. Please provide copies of any **correspondence, briefing, or minutes of meetings** between DHSC, the Home Office, or the ACMD regarding the establishment, remit or scope of the review.
8. If DHSC was consulted on or contributed to the formulation of any **terms of reference or specifications** for that review, please provide copies of those documents and any comments or submissions from DHSC officials or Ministers.
9. Given that **any potential contract-award and evidence-gathering phases** are now concluded, please confirm whether **any relevant information** is being withheld on commercial-confidentiality grounds and the reasons for doing so.

This request forms part of the ongoing correspondence already acknowledged by the Department, including the **open letter of June 2025**, *Discrimination by Design* (September 2025), and **Supplementary Annexes D and E** (October 2025), together with my formal submission to the **Home Office-led call for evidence**, which closed on 17 October 2025.

I appreciate that officials must be able to provide frank advice to Ministers without fear of premature disclosure. However, the information sought here concerns work completed and implemented in 2018 and subsequent follow-up **actions up to and including the period in which the Home Office issued the requirement for the now-concluded call for evidence.**

Given the passage of time and the closure of the public evidence-gathering process, the balance of the public interest now lies firmly in transparency over any pre-existing policy rationale and equality considerations rather than preservation of Government's need for deliberative space. Accordingly, any reliance on section 35(1)(a) or related exemptions should be accompanied by the Department's full public-interest test.

Please confirm receipt of this request and respond within twenty working days as required by the Act.

Yours faithfully

Pete Lindsay

Annex G – Initial June Engagement with Government

Pete Lindsay

Personal Details redacted for privacy

16 June 2025

The Rt Hon Yvette Cooper MP
Home Secretary

Dear Home Secretary

Open Letter: Ensuring Lawful and Equitable Access to Clinically Appropriate Cannabis-Based Products for Medicinal Use (CBPMs)

I am writing to bring to your urgent attention the significant challenges faced by disabled patients, including myself, in accessing and managing prescribed cannabis-based products for medicinal use (CBPMs). As someone living with a disabling neurological condition, I experience acute symptoms daily and rely on CBPMs to manage my condition with a degree of daily normality. Without appropriate and timely access to such medication I would be largely wheelchair-bound, unable to walk or speak.

Unlike many with this condition, I am fortunate not to suffer seizures or extreme, constant pain. However, the complexity and variability of my symptoms require clinically appropriate and reliable methods of consumption to achieve effective symptom relief. For example, this may include rapid-onset forms of administration such as vaporisation or combustion (smoking) — where other oral methods are insufficiently responsive and time-critical relief is needed. Current policy effectively restricts lawful, practical access to these treatments, undermining both the purpose of the underlying legislation and the rights of disabled people to health and equality **(See Annex A)**.

One critical issue concerns the legal constraints on the administration of CBPMs. While multiple forms of CBPMs are prescribed, existing regulations limit how these medicines can be used practically by patients. Some clinically effective methods are not legally recognised for patient self-administration, complicating efforts to manage symptoms safely and effectively.

This situation undermines both the rule of law and the principle of equitable healthcare. It also exposes vulnerable patients, including those with chronic pain, neurological conditions or treatment-resistant conditions, to significant financial, legal and health risks. The current framework creates a structurally discriminatory and legally precarious two-tier system that fails to meet the UK's obligations under domestic and international law, including rights to health, private life, and non-discrimination.

Moreover, inconsistencies between the Misuse of Drugs Regulations and the Equality Act 2010 create a precarious legal environment for patients, often resulting in confusion and risk in daily medication management, healthcare interactions, and contact with law enforcement.

I also want to highlight ongoing concerns around awareness and education within the medical, policing, and disability assessment communities regarding medical cannabis use. These gaps exacerbate challenges faced by patients and may contribute to unjustified legal and social risks.

I would therefore respectfully urge your department to consider supporting the actions suggested in outline at **Annex B**, incl but not limited to:

- Address inconsistencies that place patients at legal and practical risk

and

- Ensure that disability rights legislation is fully integrated and respected within wider policy frameworks – particularly;

- ❖ Prioritise education initiatives across the NHS, policing bodies and disability assessment communities to improve understanding and support for medical cannabis patients.
- ❖ Review and update clinical guidance to reflect current evidence and patient needs, including methods of administration.
- ❖ Consider mechanisms to enable practical, safe access to clinically appropriate CBPM administration methods.

Although I'm now medically retired due to my disability, my background includes a reasonably successful career across various Government Departments. This has given me broad insight across government processes and reinforces my confidence in the importance of evidence-based, clear policy, and effective interdepartmental collaboration to address the challenges outlined.

Given that the Spending Review has now provided clarity across government on both budgets and policy priorities, the forthcoming summer recess and subsequent conference season represent significant opportunities for cross-governmental decision-making and subsequent ministerial approval.

I also recognise that whilst providing opportunities, these timing factors may also impact Department's ability to prioritise or resource policy changes immediately. Therefore, I hope this letter and its accompanying annexes will serve as a foundation for action. I would welcome a response from your department within the usual correspondence obligations set by the Cabinet Office. I am also keen for any opportunity to contribute further to discussions on policy improvement and implementation. Following recess and the party conference season, I hope there may be further opportunities to advance these vital issues within government priorities.

Thank you for your time and consideration. I look forward to your response and the possibility of engaging further on this critical issue.

This letter has been issued concurrently to relevant ministers, departments, regulators, and public bodies in recognition of its cross-government implications. **See Annex C** for initial distribution list.

Personal Details redacted for privacy

Annex A: Key Context, Legal Framework, and Policy Considerations on Medical Cannabis Access and Use

1. Inconsistencies Between Drug Legislation and Disability Rights

The Equality Act 2010 places a legal obligation on public bodies to make reasonable adjustments for disabled people and prohibits discrimination. As primary legislation, it has precedence over secondary legislation such as drug regulations.

However, the Misuse of Drugs Regulations and Home Office policy create a conflicting environment where patients lawfully prescribed CBPMs risk legal jeopardy for using their medicine in ways necessary to manage their disability effectively.

This legal tension is not currently addressed in either drug policy or wider Government policy, leaving patients vulnerable to enforcement actions despite being protected under disability law.

2. Driving, Policing, Education, and Enforcement

The DVLA issues medical licenses to patients who are prescribed CBPMs.

However, police forces often lack clear guidance and training on handling patients prescribed medical cannabis, resulting in inconsistent enforcement and unnecessary legal risks for patients.

There is inconsistency in assessments of fitness to drive, especially where symptoms of the underlying condition (e.g., limb weakness, stability issues) may impact impairment tests independently of medication use.

Many prescribed patients with neurological conditions (such as Functional Neurological Disorder) or musculoskeletal conditions may exhibit physical symptoms (limb weakness, balance problems) that affect their performance in standard impairment tests — regardless of whether they are impaired by medication. The legal impairment tests (e.g., walking heel-to-toe, standing on one leg) do not therefore always adequately distinguish between disability symptoms and true impairment due to CBPM use, creating significant risks in both legal and driving contexts

This means that there is currently inadequate clinical or legal differentiation between these disability symptoms and true impairment due to CBPM use.

Education initiatives for law enforcement, medical professionals and disability assessment communities are urgently needed to ensure policies are implemented with awareness of disability rights and medical necessity.

3. Medical Cannabis Prescription and Administration Challenges

The UK's legal framework permits prescription of cannabis-based products for medicinal use (CBPMs) under very limited conditions and by specialist doctors only. However, regulations such as the Misuse of Drugs Regulations 2001 (especially Regulation 16A) restrict how prescribed patients can administer these medicines themselves.

This creates a disconnect between what is medically appropriate and what is legally permitted for self-administration, especially regarding the consumption method, which can be critical to symptom relief.

Although studies show that vaporisation offers a cleaner delivery of cannabinoids than combustion, some patients report that smoking provides faster and more sustained relief. These differences in subjective efficacy may warrant further investigation into comparative pharmacokinetics and real-world outcomes across administration method.

These patient-reported outcomes suggest that, for certain disabling or acute-onset conditions, **combustion may remain the most clinically effective method** in practice — even if not the most medically desirable. Further research is needed to clarify differences in efficacy and duration between methods.

4. Clinical Guidance and NHS Prescribing Constraints

NICE Guideline NG144 (Medicinal Cannabis) sets out evidence-based recommendations but currently reflects a cautious stance, partly due to limited high-quality evidence.

NHS prescribing of CBPMs remains highly restricted compared to private clinics, resulting in access inequalities. The regulatory framework for private prescribing is established but lacks integration with NHS commissioning, causing patient confusion and inconsistent care.

Updates to clinical guidance and NHS prescribing frameworks to explicitly consider patient-centred administration methods and practicalities are essential.

5. International Travel Considerations

Patients travelling abroad with legally prescribed CBPMs face a complex landscape. While UK law allows travel with prescriptions, this is conditional on the destination country's laws, which vary widely. Clearer guidance is needed to support patient mobility.

6. International Comparisons and Structural Policy Issues

The UK's approach to medical cannabis remains grounded in a "control by exception" framework, where cannabis-based products are controlled substances first and medicines second.

This contrasts with models in many other countries (e.g., Germany, Canada, Israel, parts of Australia and the USA), where medical cannabis is regulated under mainstream medicines law with appropriate clinical safeguards.

The UK's model creates regulatory rigidity and prevents the integration of CBPMs into normal clinical pathways and patient rights frameworks, including those protected under the Equality Act 2010.

In Germany, for example, prescribed cannabis is covered under statutory health insurance, and administration methods are determined by clinical need and patient circumstances. In Canada, medical cannabis is governed by distinct but integrated legislation (Cannabis Act, 2018), balancing public health with patient rights and protections.

The UK's regulatory stance is now a significant outlier internationally, limiting innovation, clinical development, and patient outcomes in comparison to peer countries.

References

- Misuse of Drugs Regulations 2001, Regulation 16A

- Equality Act 2010

- NICE Guideline NG144, Medicinal Cannabis

- DVLA medical standards and guidance

Annex B – Indicative Departmental Actions to Support Equitable Access to CBPMs

This annex outlines suggested areas of responsibility and potential actions across UK Government departments and key public bodies. It is intended to support a constructive, coordinated response to the concerns raised in the main letter and annex.

Home Office

- Review the impact of Regulation 16A(3), Misuse of Drugs Regulations 2001, in light of the Equality Act 2010 and the need for clinically appropriate administration. [See Annex A §1]
  Click to view source

- Clarify licensing implications for patients and clinics using lawful CBPMs via vaporization **OR** combustion. [See Annex A §2]
  Click to view source

- Lead a review of police enforcement practice relating to patients prescribed CBPMs, particularly regarding methods of consumption. [See Annex A §2]
  Click to view source

- Support consistent interpretation of lawful possession and administration across law enforcement bodies and regional forces. [See Annex A §2]
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Metropolitan Police Service

- Ensure clear guidance for officers on how to engage with patients lawfully prescribed CBPMs. [See Annex A §2]
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- Integrate lawful CBPM use into stop and search protocols, respecting disability rights and clinical need. [See Annex A §2]
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- Provide operational training on equality law as it relates to disabled CBPM patients. [See Annex A §1 and §2]
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- Participate in joint reviews with the CPS and Home Office to avoid discriminatory or inconsistent enforcement. [See Annex A §2]
  No current strategy or delivery plan appears to be in place.

- Support balanced use of impairment testing to ensure methods distinguish disability symptoms from intoxication. [See Annex A §2]
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Ministry of Justice / Crown Prosecution Service

- Clarify prosecutorial discretion for patients holding valid CBPM prescriptions. [See Annex A §1 and A §2]
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- Issue guidance reflecting disability rights and the clinical basis for lawful CBPM use. [See Annex A §1]
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- Coordinate with Home Office and policing bodies to reduce inconsistent charging and enforcement outcomes. [See Annex A §2] – for context, the most recent published position by this administration is was published by the previous Government in 2022. **From Harm to Hope remains the official framework** for UK drugs policy. A revised national drugs strategy hasn't yet been published, nor has a formal successor white paper been launched
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Department of Health and Social Care (DHSC)

- Review NICE guidance (e.g. NG144) to ensure equitable access to CBPMs, including for acute or rapid-onset needs. [See Annex A §4]
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- Ensure NHS protocols and digital systems support valid private prescriptions and CBPM patient records. *(data published 2023)* [See Annex A §4]
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NHS England

- Work with DHSC to remove systemic barriers to lawful prescription and delivery of CBPMs. [See Annex A §4]
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- Clarify guidance to Integrated Care Boards (ICBs) on care pathway support for CBPM patients. [See Annex A §4]
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- Address confusion in primary care prescribing for patients with lawful private CBPM prescriptions. [See Annex A §4]
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Department for Transport / DVLA

- Update official guidance on driving and cannabis, explicitly recognising lawful medical use and differentiating from misuse. [See Annex A §2]
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- Review the fairness and medical accuracy of impairment-based testing, especially for patients with neurological and / or functional disabilities. [See Annex A §2]
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- Promote engagement with clinicians and patient advocates to ensure assessments are lawful, evidence-based and non-discriminatory. [See Annex A §2]
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Cabinet Office / Disability Unit

- Ensure compliance with the Public Sector Equality Duty across departments. [See Annex A §1]
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- Lead cross-government coordination on disability-related implications of CBPM policy. [See Annex A §6]
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- Champion consistent policy alignment with the Equality Act and accessible healthcare obligations. [See Annex A §1 and §6]
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Department for Work and Pensions (DWP)

- Ensure that disability assessors (e.g. PIP, ESA, WCA contractors) are trained on the lawful prescription and administration of CBPMs. [See Annex A §1, §2]

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- Review existing policy to ensure that prescribed CBPM use does not lead to inappropriate benefit denial or negative scoring in functional assessments. [See Annex A §1, §2]

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- Integrate CBPM-related guidance into Access to Work decision-making, ensuring reasonable adjustments are not refused due to cannabis stigma or policy misinterpretation. [See Annex A §1, §3]

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- Audit and report on existing cases where CBPM patients have been disadvantaged due to administrative or assessor-level misapplication of [See Annex A §1, §3]

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Annex C: Initial Distribution List

Home Secretary	Rt Hon. Yvette Cooper MP
Health & Social Care Secretary	Rt Hon. Wes Streeting MP
Transport Secretary	Rt Hon. Heidi Alexander MP
Justice Secretary	Rt Hon. Shabana Mahmood KC MP
Work & Pensions Secretary	Rt Hon. Liz Kendall MP
Cabinet Office	Rt Hon. Nick Thomas-Symonds MP
Metropolitan Police Commissioner	Sir Mark Rowley QPM
Mayor of London	Sadiq Khan
Chief Executive, NHS England	Sir James Mackey