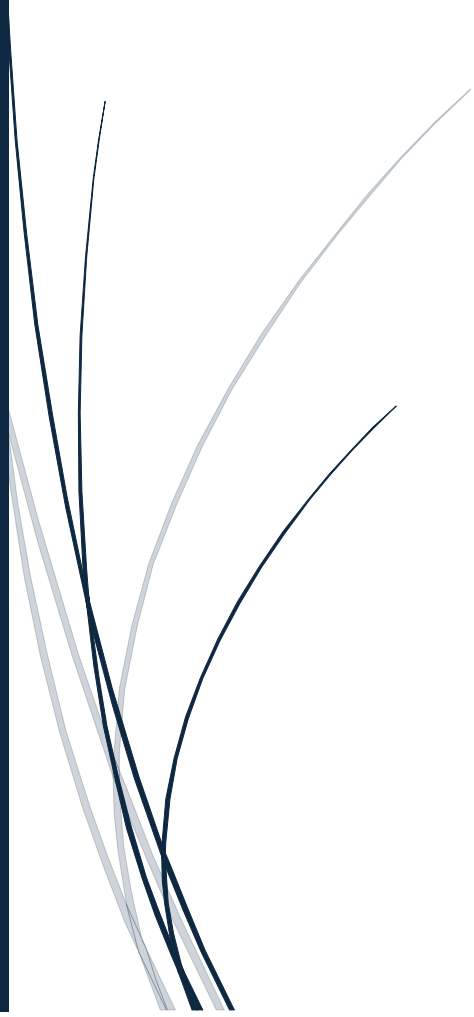
18/09/2025

Discrimination by Design

The legal flaws of Regulation 16A3



Pete Lindsay: sycharisma@googlemail.com

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 statutory review since 2018; neither **NICE** nor **MHRA** recommended a smoking prohibition. See Section 11**.**
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 Prescriptions are withdrawn if smoking is disclosed; employers discipline or dismiss; police, courts and the NHS waste resources; disabled people bear the greatest harm.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."
- **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) provides that:

“A product is not a cannabis-based product for medicinal use in humans if it is smoked.”

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 Government offered no evidence base for prohibiting smoking. The Explanatory Memorandum to the 2018 amendment stated only that *"smoking will never be acceptable."* No equality impact assessment was conducted and no consultation held. A fuller analysis of the Memorandum and these omissions is provided in Section 11 (Procedural Irregularities).

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

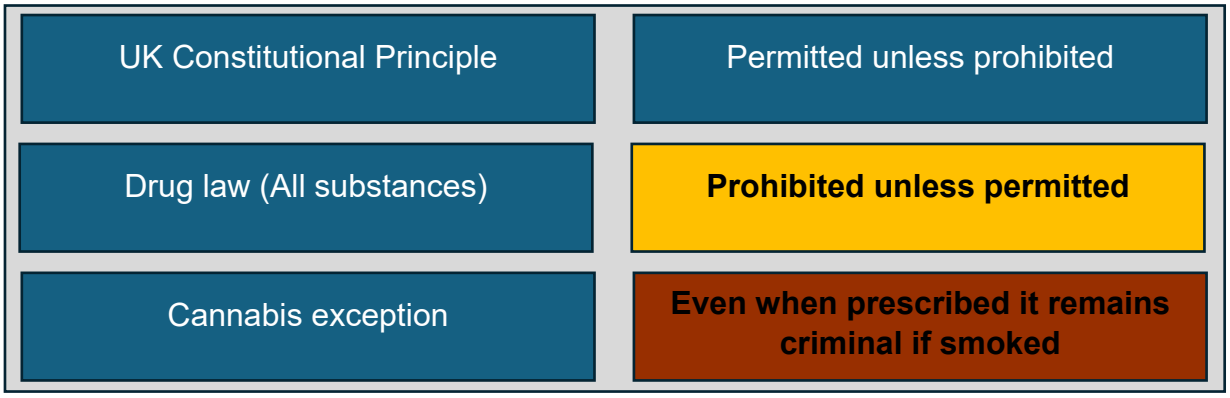


Figure 1 - Beyond Drug Law inversion

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.

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.

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

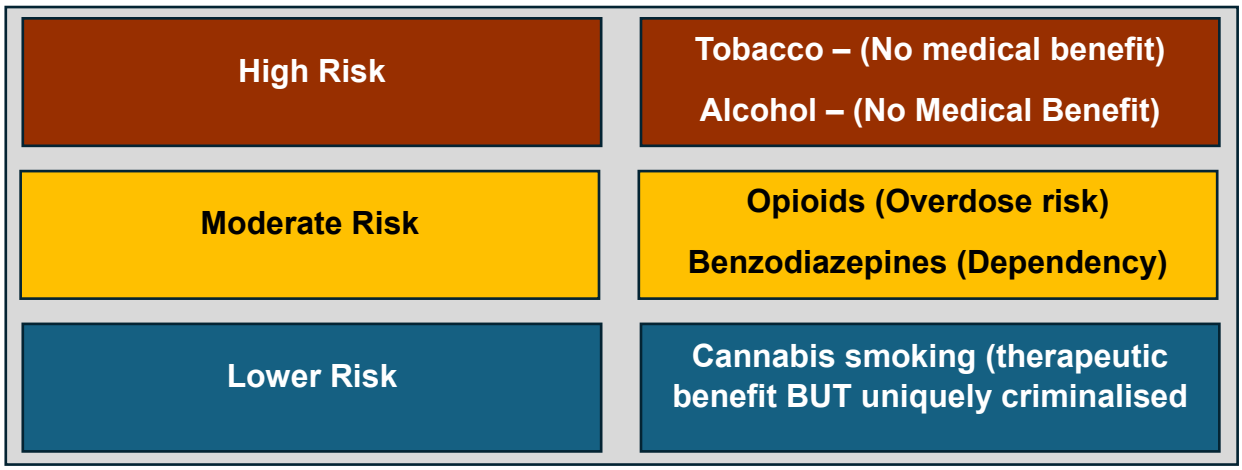


Figure 2- Relative Risk Spectrum

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.

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.

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

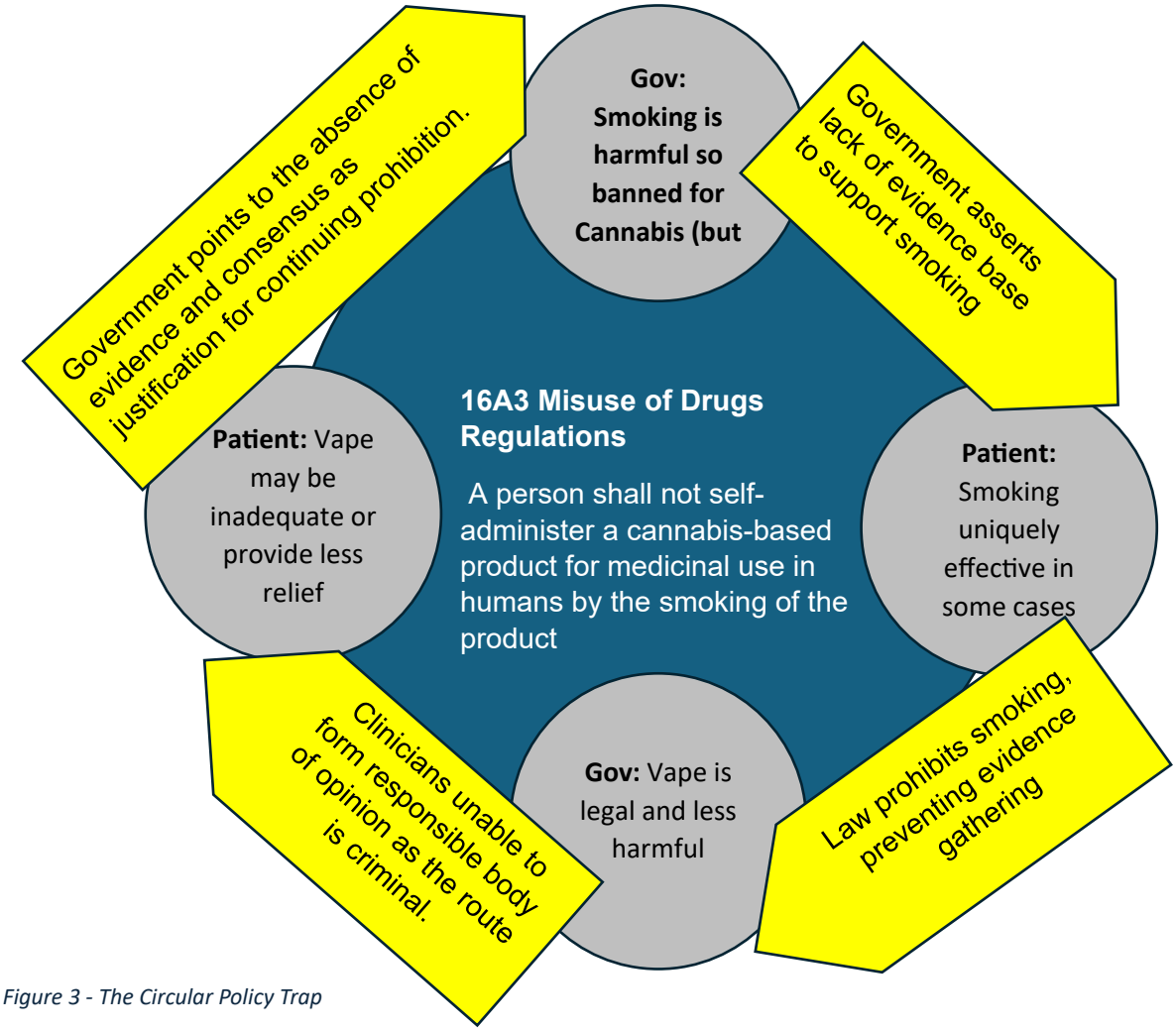


Figure 3 - The Circular Policy Trap

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.

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.

13.0 Policy 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

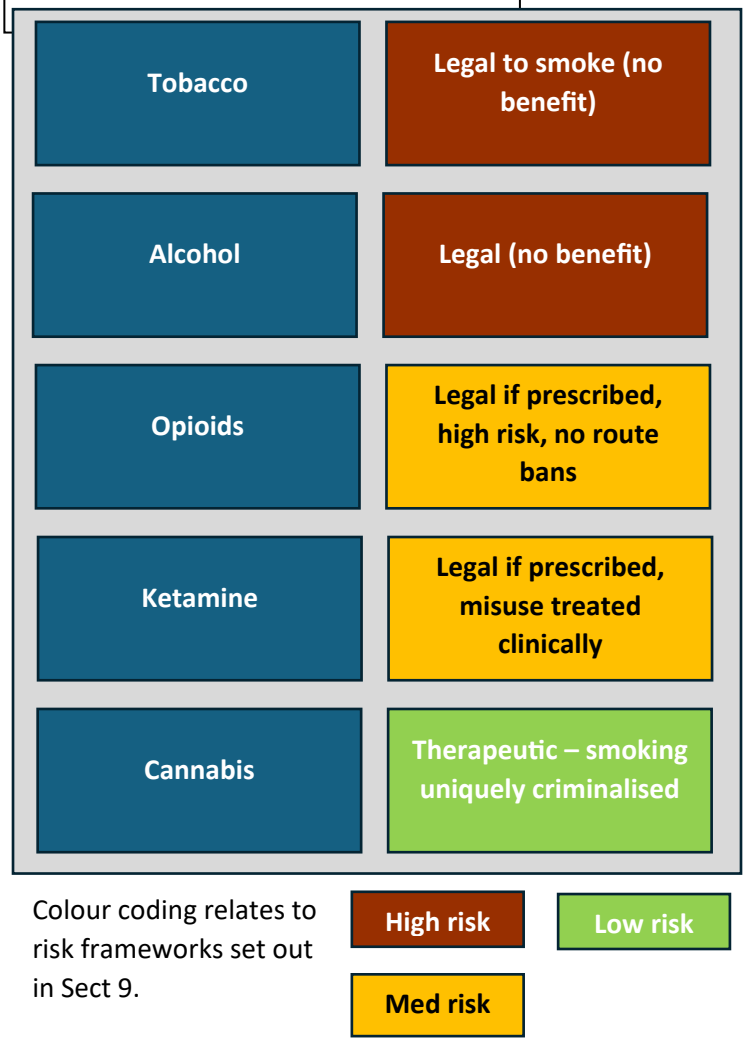


Figure 4 - Policy Contradictions

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).

---

[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.