

## Explanatory Context: Organisational Statutory Responsibilities related to SI2018/1055

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| <b>Home Office</b>   | <b>Misuse of Drugs Act 1971</b><br><b>Purpose:</b><br>To determine: <ul style="list-style-type: none"><li>- Drug Classes (A, B, C)</li><li>- seriousness of an offence (possession, supply, production)</li><li>- maximum penalties</li><li>- police powers</li></ul>   | <b>Misuse of Drugs Regulations 2001 (and amendments)</b><br><b>Purpose:</b><br>To determine scheduling for: <ul style="list-style-type: none"><li>- medical and scientific use</li><li>- prescribing rights</li><li>- Product licensing</li><li>- storage, record-keeping, destruction</li></ul> | <b>DHSC</b><br><b>Purpose:</b><br>To oversee the <b>clinical, therapeutic, and public-health implications</b> of policies affecting medicines and patient care.  | <b>DHSC responsibilities include:</b> <ul style="list-style-type: none"><li>- ensuring clinical safety and therapeutic appropriateness</li><li>- overseeing prescribing frameworks and specialist access rules</li><li>- assessing impacts on patient safety and treatment effectiveness</li><li>- aligning policy with MHRA medicines regulation</li><li>- discharging the <b>Public Sector Equality Duty</b> for health-related decisions</li><li>- evaluating impacts on disabled and clinically vulnerable patients</li></ul> | <b>ACMD</b><br><b>Purpose:</b><br>To provide <b>independent scientific, medical, and social-harm advice</b> to the Home Secretary on drug control.   | <b>ACMD responsibilities include:</b> <ul style="list-style-type: none"><li>- assessing physiological, psychological, and social harms</li><li>- evaluating therapeutic or medical value</li><li>- advising on Class (A/B/C) placement</li><li>- advising on Schedule (1-5) suitability and medical legitimacy</li><li>- reviewing evidence for policy changes</li><li>- advising on risks of criminalisation and misuse patterns</li><li>- advising on unintended consequences, misuse patterns, and proportionality of proposed controls</li></ul> |
| <b>MoJ</b><br><b>Purpose:</b><br>To regulate and oversee the <b>criminal justice consequences</b> of any change to offences, penalties, or criminalised conduct. | <b>MoJ responsibilities include:</b> <ul style="list-style-type: none"><li>- assessing new or amended criminal offences</li><li>- evaluating sentencing impacts</li><li>- modelling prison, probation, and court workload</li><li>- assessing prosecution and legal aid implications</li><li>- ensuring proportionality of criminalisation</li><li>- ensuring compliance with human rights law (ECHR)</li><li>- identifying discriminatory or unequal justice impacts</li></ul> | <b>Cabinet Office (including the Equality Hub / Better Regulation Unit)</b><br><b>Purpose:</b><br>To ensure <b>constitutional, regulatory, and cross-government compliance</b> in policy-making.   | <b>Cabinet Office responsibilities include:</b> <ul style="list-style-type: none"><li>- enforcing the Better Regulation Framework</li><li>- ensuring Impact Assessments are completed where required</li><li>- ensuring Public Sector Equality Duty compliance</li><li>- coordinating cross-departmental policy alignment</li><li>- ensuring SIs follow correct procedural routes</li><li>- reviewing whether policy choices are proportionate and evidence-based</li><li>- preventing departments from bypassing scrutiny</li></ul> | <b>Department for Education (DfE)</b><br><b>Purpose:</b><br>To uphold statutory duties relating to <b>education, safeguarding, and equality</b> , including responsibilities that extend beyond the school system.  | <b>DfE responsibilities include:</b> <ul style="list-style-type: none"><li>- discharging the Public Sector Equality Duty across all protected groups</li><li>- assessing disability, health, and inclusion impacts of government policy safeguarding children and young people affected by cross-government decisions</li><li>- ensuring non-discrimination in access to services and public functions</li><li>- providing guidance on public health messaging in educational settings contributing to cross-government equality analysis where health, or children's welfare are affected</li></ul> | <i>(Note: DfE's PSED responsibilities apply even when DfE is not the lead department.)</i>   |
| <b>Regulatory Options for the Home Office for the making of SI2018/1055 - Consequences &amp; Impacts</b>   |   |  |  |   |  |  |

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| <b>Option 1: Move Cannabis to Schedule 2 (Normal UK Model)</b> <ul style="list-style-type: none"><li>- Aligns with existing medicines regulation</li><li>- Removes logical contradiction between "no medical use" and prescribing</li><li>- Enables plant-based prescribing without discrimination</li><li>- Used by most countries with medical regimes</li></ul> | <b>Option 2: Create New Sub-Schedule (2A)</b><br><b>Bespoke but coherent framework</b> <ul style="list-style-type: none"><li>- Allows tight, bespoke controls without misclassifying medical cannabis</li><li>- Provides legal clarity without inventing narrow product-based definitions</li><li>- Supports consistent clinical guidance and predictable prescribing rules</li><li>- Maintains political caution while avoiding structural contradictions</li></ul> | <b>Option 3 (Home Office Choice): Leave Cannabis in Schedule 1 + Create 'CBPM' Category + Add Reg. 16A(3)</b> <ul style="list-style-type: none"><li>- Leaves cannabis incorrectly classified as "no medical use"</li><li>- Creates internal contradiction once prescriptions are allowed</li><li>- Imposes criminal liability for a route of administration</li><li>- Restricts access through narrow, artificial product definitions</li><li>- Generates Equality Act, PSED, and Better Regulation vulnerabilities</li></ul> |
| <b>Regulatory coherence restored</b><br>Cannabis plant and cannabis medicines sit within the same therapeutic framework; no contradiction between "medical use" and Schedule placement.  | <b>Regulatory coherence restored</b><br>A bespoke Schedule 2A creates a clear, internally consistent framework for cannabis-based medicines without misclassifying the plant or creating artificial product categories.  | <b>Regulatory coherence lost</b><br>Cannabis remains "no medical use" in Schedule 1 while cannabis medicines are permitted in Schedule 2, creating a structural contradiction at the heart of the framework.  |
| <b>Access pathway stabilised</b><br>Clinicians and pharmacists operate within familiar Schedule 2 CD processes; prescribing becomes technically straightforward.   | <b>Access pathway stabilised</b><br>Clinicians and pharmacists operate within predictable, rule-based prescribing and dispensing processes; guidance is consistent and not dependent on narrow CBPM definitions.   | <b>Access pathway destabilised</b><br>Clinicians face inconsistent rules, narrow product definitions, and route-based restrictions; prescribing depends on artificial legal categories rather than clinical judgement.  |
| <b>Equality Act exposure reduced</b><br>Disabled patients are not singled out via route-based criminal sanctions; discrimination risks fall to baseline.   | <b>Equality Act exposure minimised</b><br>No route-specific criminalisation is required; disabled patients are not singled out for differential treatment, and discrimination risks remain low.  | <b>Equality Act exposure increased</b><br>Reg. 16A(3) uniquely criminalises a lawful route of administration, disproportionately affecting disabled patients who rely on inhaled forms for therapeutic effect.  |
| <b>Research and product development unlocked</b><br>Schedule 2 licensing removes major barriers to clinical trials, manufacturing, and academic work.  | <b>Research and product development unlocked</b><br>A dedicated sub-schedule provides a stable legal basis for trials, manufacturing, and academic work without the full barriers of Schedule 1 licensing.   | <b>Research and product development constrained</b><br>Schedule 1 status maintains significant barriers to clinical trials, licensing, and innovation, preventing the UK from developing or evaluating plant-based products.  |
| <b>International alignment achieved</b><br>Brings UK into line with jurisdictions treating medical cannabis as a controlled medicine rather than a prohibited substance.   | <b>International alignment achieved</b><br>Brings the UK closer to jurisdictions using bespoke but coherent medical cannabis schedules, offering tight control without the contradictions of the current framework.  | <b>International alignment abandoned</b><br>No other jurisdiction splits plant and product in this way or criminalises a medical route of administration; the UK becomes a clear outlier.   |

### Why the HO chose Option 3?

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| <b>Easiest parliamentary route</b><br>Option 3 could be delivered entirely by <b>negative resolution</b> , avoiding debate and scrutiny required for Options 1 and 2. | <b>Avoided cross-government involvement</b><br>No need for agreement from <b>DHSC, MoJ, Cabinet Office, MHRA</b> by rescheduling or creating new controlled-drug categories. | <b>Enabled fastest implementation</b><br>The negative SI allowed the Home Office to move from announcement to law in weeks, not months — crucial during political pressure in 2018. | <b>Preserved maximum departmental control</b><br>HO retained full authority over cannabis by keeping the plant in <b>Schedule 1</b> , avoiding any shift of regulatory power toward DHSC/MHRA. | <b>Created the appearance of medical legalisation without substantive reform</b><br>Inventing CBPMs allowed HO to claim "medical cannabis is now legal" while avoiding broader rescheduling, market expansion, or patient-led access. |
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### Could the HO have made SI 2018/1055 without 16A(3) and how would that affect prescribed patients?

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| <b>No new criminal offence created</b><br>Removing 16A(3) would have avoided creating a unique offence for using a lawful medicine, keeping SI 2018/1055 as a technical amendment rather than criminal reform. | <b>Reduced Equality Act exposure</b><br>Without route-based criminalisation, disabled patients are not singled out for differential treatment; discrimination risk falls to baseline. | <b>Prescribing becomes clinically coherent</b><br>Clinicians could recommend inhaled administration when clinically appropriate without patients facing criminal liability for following medical advice. | <b>Patient safety improves</b><br>Patients could use the most effective and fastest-acting route of administration for symptom control without fear of enforcement or legal ambiguity. | <b>Framework becomes legally defensible</b><br>Omitting 16A(3) would preserve the HO's political caution while avoiding the structural contradiction, PSED breaches, and procedural defects generated by the offence. |
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### A workable but tightly controlled medical regime

SI 2018/1055 would still restrict access — but without creating the incoherent, discriminatory trap that now affects prescribed patients.

**Editors note:** Update v2, sect 6 to reflect options and context