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 SI2018/1056, 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; in the CBPM case, the substantive prohibitions were introduced only through the negative Regulations, escaping parliamentary scrutiny or amendment.

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.

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)