Annex E – Departmental and Cross-Government Questions

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

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

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

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

Purpose and Scope

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

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

They are intended to assist in clarifying evidential, procedural, and equality-law matters relating to Regulation 16A(3) of the Misuse of Drugs Regulations 2001, as inserted by the Misuse of Drugs (Amendments) (Cannabis-Based Products for Medicinal Use) Regulations 2018 (SI 2018 No. 1055 and SI 2018 No 1056).

Questions for the Home Office

1. **Competence and responsibility**
   How does the Home Office reconcile its statement that the Department of Health and Social Care holds medicines-policy responsibility with the fact that the Misuse of Drugs Regulations 2001 (as amended by SIs 2018 Nos. 1055 and 1056) remain within Home Office legislative competence and enforcement oversight?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Cross-Government Consistency

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

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

20. Impairment-based safeguards and cross-government consistency

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

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

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

Questions for DHSC

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

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

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

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

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

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

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

Questions for the Ministry of Justice

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

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

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

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

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

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

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

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

Questions for the Equality Hub / DfE

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

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

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

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

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

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

Questions for NHS England

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

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

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

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

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

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

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

Questions for the Metropolitan Police Service

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

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

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

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

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

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

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

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

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

Questions for MOPAC

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

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

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

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

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

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

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

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

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

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

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

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

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

Summary and Next Steps

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

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

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