ACMD

Advisory Council on the Misuse of Drugs

ACMD Chair: Prof Owen Bowden-Jones

ACMD Barriers to Research Secretary: Alex Wendland

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19 March 2021

Dear Sir or Madam,

**RE: Call for Evidence – Barriers to research for controlled drugs (excluding synthetic cannabinoids)**

The Advisory Council on the Misuse of Drugs (ACMD) is collecting written evidence from researchers regarding barriers to legitimate research with controlled drugs, other than synthetic cannabinoids, for their second report on barriers to research. We would be grateful for your written feedback in the attached questionnaire as part of this call for evidence by 31 May 2021.

The initial focus of the ACMD’s dedicated working group on this issue was to specifically consider research involving *3rd generation* *synthetic cannabinoids* which may have been impeded by regulatory controls. This advice is being drafted currently after the successful February 2020 call for evidence.

We would welcome submissions of evidence from as broad a spectrum of research institutions as possible - and would therefore be grateful if you could circulate this call for evidence to other colleagues and relevant stakeholders. We will be using your feedback to assist in formulating advice to Government.

Yours sincerely,

 

**Prof Owen Bowden-Jones Prof Roger Knaggs**

*Chair of the ACMD* *ACMD Barriers to Research working group Chair*

## ACMD Barriers to Research working group – Call for Evidence

**Please return your submission to the ACMD Secretariat at**: acmd@homeoffice.gov.uk.

How we will use your information

Respondents should note that evidence submitted will inform the development of recommendations from the ACMD and could ultimately be published. However, in the interest of confidentiality and protecting commercial interests, any information submitted will be non-attributable.

All data submitted in response to this Call for Evidence will be protected by the ACMD Secretariat in accordance with the General Data Protection Regulation (GDPR). Furthermore, Section 43(1) of the Freedom of Information Act provides an exemption for information which is a trade secret, whilst Section 43(2) exempts information whose disclosure would, or would be likely to, prejudice the commercial interests of any person (an individual, a company, the public authority itself or any other legal entity).

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| **Section 1: About yourself / your organisation****Q1. Please indicate below if the following statement is applicable:**[ ]  “My submission should be considered a personal response and therefore not representative of the organisation I work for.”[ ]  “My submission should be considered as representative of the organisation I work for.”**Q2. Please indicate which of the following best describes your organisation:**[ ]  Contract Research Organisation (CRO)[ ]  University[ ]  Charity[ ]  Company within the pharmaceutical industry[ ]  Company within the biotechnology industry[ ]  Other (*please describe below*) Click or tap here to enter text.**Q3. Please indicate which of the following best describes the type of research you undertake:**[ ]  Academic[ ]  Commercial |
| **Section 2: Legal controls** **Q4a.** **Please estimate below the proportion of your (or your organisations) research that involves controlled drugs?**Click or tap here to enter text.**Q4b. Have you (or your organisation) ever encountered or expect to encounter any barriers to research with substances controlled by the Misuse of Drugs Act other than synthetic cannabinoids?**  [ ]  Yes, for individually-named compounds[[1]](#footnote-2)[ ]  Yes, for compounds described by their chemical structure (i.e. a ‘generic definition’)[[2]](#footnote-3) [ ]  No **Q5. Please indicate below any barriers that the current legislation relating to controlled drugs impose on you or your organisation (please be specific to what processes cause these):**[ ]  Regulatory (*please describe below*)Click or tap here to enter text.[ ]  Financial (*please describe below*)Click or tap here to enter text.[ ]  Time (*please describe below*)Click or tap here to enter text.[ ]  Other (*please describe below*)Click or tap here to enter text.[ ]  None**Q6. If you (or your organisation) consider barriers to research are imposed as a result of current legislation relating to controlled drugs, do you believe that these barriers have impact on the type or extent of the research you are able to carry out?**[ ]  Yes (*please describe below*)Click or tap here to enter text.[ ]  No**Q7a. Have you (or your organisation) ever applied for a controlled drugs licence?**[ ]  Yes [ ]  No (*please skip to question 8*)**Q7b. How many controlled drug licences do currently you (or your organisation) hold? (Please include type and estimates of number of sites)**Click or tap here to enter text.**Q7c. Estimate the length of time (start to finish) it takes for an application for a new licence from starting to approval.**Click or tap here to enter text.**Q7d. Approximately how many hours does the application process take you (or your organisation) for a new licence?** Click or tap here to enter text.**Q7e. Estimate the length of time (start to finish) it takes to renew a licence from starting to approval.**Click or tap here to enter text.**Q7f. Approximately how many hours does the application process take (you or your organisation) to renew a licence?**Click or tap here to enter text.**Q7g. Approximately how many additional hours per year does it take you (or your organisation) to comply with the conditions or requirements of your current licence?** Click or tap here to enter text.**Q7h. If you (or your organisation) are on time limited grants what percentage of the time on a typical grant does the answers to question 7c to 7e represent, and could you start this process before the grant starts?**Click or tap here to enter text.**Q7i. Approximately how much money is spent on obtaining and complying with the drugs licence as a percentage of a typical grant, yearly budget, or appropriate comparative metric?**Click or tap here to enter text.**Q8a. Have you (or your organisation) ever applied for an import/export licence for drugs?**[ ]  Yes [ ]  No (*please skip to question 9*)**Q8b. How many import/export licences do you (or your organisation) apply for (per year)?**Click or tap here to enter text.**Q8c. Approximately how many hours do you (or your organisation) spend applying for import/export licences (per year)?**Click or tap here to enter text.**Q9a. Have you (or your organisation) ever made use of the** [**‘exempt product’ definition**](https://www.legislation.gov.uk/uksi/2001/3998/regulation/2)  **within the Misuse of Drugs Regulations 2001?**[ ]  Yes (*please explain in what capacity below*)[ ]  No (*please explain the factors in your decision not to use it then proceed to question 10*)Click or tap here to enter text.**Q9b. Have you (or your organisation) experienced issues using the exempt product definition?**Click or tap here to enter text.**Q10. Which compounds do you require for your research and in what form are they stored (specifically is it stored in a form where the controlled compound can be recovered), for each compound please estimate how much (by weight) is required for the tests you carry out, how much (by weight) you store, if you buy or produce it and whether it is administered to an animal or a human being? (add text or use the provided table)**Click or tap here to enter text.

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| --- | --- | --- | --- | --- | --- |
| Compound | Storage | Test weight | Stored weight | Buy/Produce | Subject |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*(Add rows as required)* |
| **Section 3a: Case studies of barriers to research with controlled drugs during in vitro drug discovery research***Please describe any barriers to research you have experienced as a result of current legislation.**It would be helpful if respondents could describe the drug/range of drugs that they have attempted to conduct research with, the time-frame in which the case studies took place, what regulations caused these barriers, and the result of the barriers (e.g. a delay, a change impact on the type or extent of the research you are able to carry out).*Click or tap here to enter text. |
| **Section 3b: Case studies of barriers to research with controlled drugs during in vitro drug development research***Please describe any barriers to research you have experienced as a result of current legislation.**It would be helpful if respondents could describe the drug/range of drugs that they have attempted to conduct research with, the time-frame in which the case studies took place, what regulations caused these barriers, and the result of the barriers (e.g. a delay, a change impact on the type or extent of the research you are able to carry out).*Click or tap here to enter text. |
| **Section 3c: Case studies of barriers to research with controlled drugs during animal studies***Please describe any barriers to research you have experienced as a result of current legislation.**It would be helpful if respondents could describe the drug/range of drugs that they have attempted to conduct research with, the time-frame in which the case studies took place, what regulations caused these barriers, and the result of the barriers (e.g. a delay, a change impact on the type or extent of the research you are able to carry out).*Click or tap here to enter text. |
| **Section 3d: Case studies of barriers to research with controlled drugs during human studies***Please describe any barriers to research you have experienced as a result of current legislation.**It would be helpful if respondents could describe the drug/range of drugs that they have attempted to conduct research with, the time-frame in which the case studies took place, what regulations caused these barriers, and the result of the barriers (e.g. a delay, a change impact on the type or extent of the research you are able to carry out).*Click or tap here to enter text. |
| **Section 3e: Case studies of barriers to research with controlled drugs that does not belong in 3a-d***Please describe any barriers to research you have experienced as a result of current legislation.**It would be helpful if respondents could describe the drug/range of drugs that they have attempted to conduct research with, the time-frame in which the case studies took place, what regulations caused these barriers, and the result of the barriers (e.g. a delay, a change impact on the type or extent of the research you are able to carry out).*Click or tap here to enter text. |
| **Section 4: Potential solutions to barriers to legitimate research with controlled drugs***It would be helpful if respondents could note any potential solutions to either the barriers to research they have experienced directly, or any other perceived barriers to research whilst also protecting public health by reducing access to substances that may be subject to misuse with consequent adverse health consequences.* Click or tap here to enter text. |

1. The Misuse of Drugs Act and Regulations list a number of individually-named drugs such as mescaline, cocaine, morphine, 2,5-Dimethoxy-α,4-dimethylphenethylamine (etc.) [↑](#footnote-ref-2)
2. The Misuse of Drugs Act and Regulations list a number of generic definitions to capture a whole range of chemically-related compounds. For example, fentanyl-analogues are captured by a generic definition that starts “any compound.. structurally derived from fentanyl by modification in any of the following ways: ….” [↑](#footnote-ref-3)