ACMD

Advisory Council on the Misuse of Drugs

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Monday 10th February 2020

Dear Sir or Madam,

**RE: Call for Evidence – Barriers to Research**

The Advisory Council on the Misuse of Drugs (ACMD) is collecting written evidence from researchers regarding barriers to legitimate research with controlled drugs. We would be grateful for your written feedback in the attached questionnaire as part of this call for evidence by Thursday 9th April 2020.

Further to productive conversations between the ACMD and research community representatives, the ACMD has established a dedicated working group to gather further evidence to consider the barriers to legitimate research with controlled drugs.

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 as widely as possible this call for evidence to other colleagues and relevant stakeholders where possible. We will be using your feedback to assist in formulating advice to Government.

The working group will be focussing initially on research which may have been impeded by legal controls intended to cover *synthetic cannabinoids*. We will also take any opportunities which present themselves to evaluate the scale of issues for research involving *other* controlled drugs and barriers to research, more generally.

We would like to thank you for your assistance in this matter and look forward to hearing from you.

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 consider the following information before completing the questionnaire:**

Completing the questionnaire

Although your expertise may be better suited to tackling only a subset of the following questions, it would be helpful if you were to consider every question in the questionnaire.

Section 3 may only be relevant to research groups conducting drug discovery research. Only those who have had their research affected by legal controls intended to capture synthetic cannabinoids should complete Section 4.

A free text box has been included in the questionnaire (Section 5) for respondents to include any comments relating to Barriers to Research that they feel have not been covered by this questionnaire.

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 research:**[ ]  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[ ]  Industrial |
| **Section 2: Legal controls** **Q4. Have you encountered any barriers to research with substances controlled by the Misuse of Drugs Act?** [ ]  Yes, for individually-named compounds[[1]](#footnote-1)[ ]  Yes, for compounds described by their chemical structure (i.e. a ‘generic definition’)[[2]](#footnote-2) [ ]  No (*please estimate below the proportion of your research that involves controlled drugs - before proceeding directly to ‘Section 5’*) Click or tap here to enter text.**Q5. Do you have access to computational software to determine whether compounds are subject to legal controls?** [ ]  Yes (*please describe below*)[ ]  No (*where you use other methods to determine whether or not compounds are subject to legal controls - e.g. specific laboratory assays or analytical equipment - please specify below*)Click or tap here to enter text.**Q6. Has your research been affected by legal controls intended to capture synthetic cannabinoids?** [ ]  Yes - I carry out research on synthetic cannabinoids[ ]  Yes - I carry out research on compounds which are not synthetic cannabinoids, but were inadvertently caught by legal controls intended to capture synthetic cannabinoids[ ]  No - My research has not been affected by these controls (*please specify below, if you are able to, the family of compounds which you research – and skip ‘Section 4’ of the questionnaire when you reach it*)Click or tap here to enter text. **Q7. Please indicate below any burdens you consider are imposed as a result of current legislation relating to controlled drugs:**[ ]  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**Q8. If you have experienced any burdens, have they influenced the direction of your research?**[ ]  Yes[ ]  No |
| **Section 3: Techniques used in your research***NOTE: This section relates to drug-discovery research – if the following questions are not relevant for you/your organisation, please proceed directly to ‘Section 4’. Furthermore, if you consider this section refers to confidential information, you should not feel obliged to answer it – simply note that this is the case.**This section has been included in the questionnaire so that the ACMD can obtain an approximation of the quantity (mass) of a compound that an organisation would need to legitimately possess in order to conduct the “hit to lead” stage of drug discovery, and an approximation of the quantity (mass) of that compound that would be recoverable after all of the relevant “hit to lead” testing has been completed.**By ‘recoverable’ we mean recoverable by readily applicable means in a yield that would constitute a risk to health.***Q9. Where possible, please provide - with evidence - the quantity (mass) of compound that is typically consumed in each of the following assay types:**a. Quality controlb. Pharmacological Activity Testingc. Physicochemical assessmentd. Absorption, Distribution, Metabolism, Excretion (ADME)e. Selectivityf. Repeat assays (where necessary)Click or tap here to enter text.**Q10. Where relevant, please provide details of any other assays which your institution would need to carry out in the “hit to lead” stage of drug discovery - alongside the quantity (mass) of compound (with evidence) that is typically consumed in that assay.**Click or tap here to enter text.**Q11. Where your institution utilises high throughput liquid handling techniques in your “hit to lead” testing programme(s), what quantity (mass) of residue of the compound is typically recoverable (if any)?** Click or tap here to enter text.**Q12.** **Where your institution utilises methods *other than* high throughput liquid handling techniques in your “hit to lead” testing programme(s), what quantity (mass) residue of the compound is typically recoverable (if any)?**Click or tap here to enter text.**Q13.** **Are the compounds tested in your institution’s “hit to lead” programmes recoverable after dissolution and dilution in organic solvents, such as dimethyl sulfoxide (DMSO)?**Click or tap here to enter text. |
| **Section 4: Research affected by legal controls intended to capture synthetic cannabinoids** NOTE: This section relates to research with synthetic cannabinoids – if the following questions are not relevant for you/your organisation, please proceed directly to ‘Section 5’.**Q14.** **At what point in your research process is CB1 agonist activity assessed, if at all?**Click or tap here to enter text.**Q15. What typical test system(s) would your organisation (or the CRO to which these assays are outsourced) use to provide functional CB1 agonist assays?**Click or tap here to enter text.**Q16. What proportion of compounds (estimate) in your chemical library:** * **were controlled prior to the December 2016 amendment to the Misuse of Drugs Act[[3]](#footnote-3) intended to generically define third-generation synthetic cannabinoids?**

 Click or tap here to enter text.* **were controlled by the generic definition for third-generation synthetic cannabinoids following the December 2016 amendment to the Misuse of Drugs Act (i.e. prior to the November 2019 revision of that definition[[4]](#footnote-4))?**

 Click or tap here to enter text.* ***remain* controlled by the generic definition for third-generation synthetic cannabinoids following the November 2019 revision of that definition? Of these, what proportion (estimate) are likely to exhibit CB1 receptor agonist activity?**

Click or tap here to enter text.* **are undetermined as to whether or not they are are controlled by the generic definition for third-generation synthetic cannabinoids following the November 2019 amendment (without further testing)?**

 Click or tap here to enter text.**Q17. Over the course of a targeted chemical synthesis (for example, when researching novel synthetic techniques), have you ever found that an end product - or any other reaction intermediate in the synthetic pathway – has been captured by the November 2019 revision to the generic definition for third-generation synthetic cannabinoids?**Click or tap here to enter text.**Q18.** **Does your organisation have the capability to either a) interrogate your chemical library to determine CB1 agonism, or b) contract a CRO which is capable of interrogating your chemical library to determine CB1 agonism?** Click or tap here to enter text.**Q19. Please provide an indication of the resources (time, manpower, equipment, etc) that are required for your organisation (or the CRO to which these assays are outsourced) to interrogate your chemical library to determine CB1 agonism.**Click or tap here to enter text.**Q20**. **What quantity (mass) of a compound would your organisation (or the CRO to which these assays are outsourced) require in order to be able to assess CB1 agonism?**Click or tap here to enter text.**Q21.** **What – if any - organisational approval processes/controls are in place to identify unusual patterns of activity with controlled drugs (e.g. to track samples, record testing data, storage requirements, etc)?**Click or tap here to enter text.**Q22. Could you/your organisation easily adopt (if not done already) routine stock takes to identify unusual patterns of activity?** Click or tap here to enter text.**Q23.** **Following the 2019 amendment to the generic definition for third-generation synthetic cannabinoids, has your institution encountered – or do you expect to encounter, going forward - any barriers to research resulting from legal controls intended to capture synthetic cannabinoids?**Click or tap here to enter text. |
| **Section 5: Any additional comments***Please submit below any comments relating to barriers to research which you feel the questionnaire was unable to capture.* *While the initial focus of the ACMD Barriers to Research working group is to specifically consider research which may have been impeded by legal controls intended to cover synthetic cannabinoids, the working group would also like to take the opportunity to evaluate the barriers to researching with controlled drugs more generally.*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-1)
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-2)
3. <https://www.legislation.gov.uk/uksi/2016/1109/made> [↑](#footnote-ref-3)
4. <http://www.legislation.gov.uk/ukdsi/2019/9780111187302> [↑](#footnote-ref-4)