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,

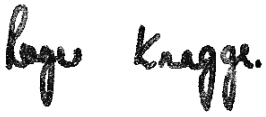
RE: Call for Evidence – Barriers to research for controlled drugs (excluding synthetic cannabinoids)

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
Chair of the ACMD

Prof Roger Knaggs
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).

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*)

Professional Leadership Body -Royal Pharmaceutical Society

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?

Indirectly involved via RPS membership

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]

☒ Yes, for compounds described by their chemical structure (i.e. a 'generic definition')[2]

☐ No

[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.)
[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: …."

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*)

Regulatory Inflexibility e.g. applying for new controlled drug licences before a clinical study could be initiated or for that matter undertaking basic research in an academic institution

☐ Financial (*please describe below*)

Click or tap here to enter text.

☒ Time (*please describe below*)

During COVID 19 the time lags were enhanced and hindered grant applications and funding and there are no signs that this will improve in the near future. Communications between Home Office Licencing unit and Academics is one way.

☐ 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*)

One example is that an academic scientist can research the detection of substance in biological fluids but cannot purchase reference standards to confirm identification. Also the possession of schedule 1 substances by pharmacists is ambiguous and more clarity is needed.

☐ 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)

The RPS has just recently renewed its Controlled Drug Licence for its museum and occupied the museum officer significant and time effort to apply for.

Q7c. Estimate the length of time (start to finish) it takes for an application for a new licence from starting to approval.

It can take days if not weeks for someone completing a new application to read, understand and collect the detailed and extensive information required, including what locks are in your premises and the type of alarm system, while this level of detail is understandably required for a stand alone organisation to obtain a licence, the process could be trimmed down for a recognised research institution who wish a controlled drugs licence purely for research. In addition we are aware that some institutions are waiting for their Controlled Drug Licences as they are non COVID related. We are aware of applications submitted in August 2020 have been put on hold indefinitely as they are not related to COVID 19 research.

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.

We believe this process is quicker but still requires confirmation and rechecking of the information provided.

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?

Given that the cost new is over £3000 and to renew is around £1000-£1500 and does not include the costs of ensuring compliance; this would prevent some researchers from applying for smaller grants.

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 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)

The Royal Pharmaceutical Society stores and exhibits a variety of controlled drug substances in different formulations and drug products of historical interest for educational purposes

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

A licence is required to purchase and possess reference standards and also precursor molecules which researchers need access to develop analytical methods. In addition, this also applies to borderline substances

Researchers need to have exemptions and flexibilities to be able to purchase and possess these materials as exists in countries like Israel.

Click or tap here to enter text.

Section 3c: Case studies of barriers to research with controlled drugs during animal studies

A licence is required to purchase and possess reference standards and also precursor molecules which researchers need access to develop analytical methods. In addition, this also applies to borderline substances

Researchers need to have exemptions and flexibilities to be able to purchase and possess these materials as exists in countries like Israel.

Click or tap here to enter text.

Section 3d: Case studies of barriers to research with controlled drugs during human studies

As above.

In addition, the supply of clinical material for testing in humans is further complicated as the shipment, storage and use of investigational medicinal product is too restrictive and hindering research to detriment of UK life sciences.
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).

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Section 4: Potential solutions to barriers to legitimate research with controlled drugs

Accelerate applications and reduce costs for new licences

Provide special exemptions to Academic Researchers who are designated as subject matter experts and/or Key Opinion Leaders. e.g. a simplified CD licence purely for research. There could be a lead researcher who is named as being responsible and ensuring safe storage etc.
It is our belief that this regulatory and legal flexibility would allow more fundamental and applied to occur in the UK as demonstrated in Israel were such flexibility allowed research in this arena to flourish.

Click or tap here to enter text.