

ACMD

Advisory Council on the Misuse of Drugs

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Kit Malthouse MP
Minister of State for Crime, Policing and Justice
2 Marsham Street
London, SW1P 4DF

30th July 2021

Dear Minister,

Re: Considerations of barriers to research Part 1: Synthetic cannabinoid receptor agonists (SCRA)

We are pleased to enclose the report of the Advisory Council on the Misuse of Drugs (ACMD) on barriers to research with synthetic cannabinoid receptor agonists (SCRA). The ACMD was commissioned in 2017 to advise the government on inadvertent control of non-SCRA compounds caused by the third generation generic SCRA definition. The ACMD provided some initial advice in late 2017; the short-term suggestions were accepted but long-term suggestions were deemed infeasible. This advice intends to provide some additional long-term options. This report only discusses barriers to research caused by the third generation generic SCRA definition. Barriers to research with controlled drugs more generally (not specific to compounds controlled by the generic third generation SCRA definition) will be addressed in a future report.

The objective of this report is to facilitate high quality research in the UK. To collect evidence about the barriers to research the working group had a call for evidence, met with the research community, and considered international approaches. After identifying the barriers to research, they evaluated several options against how well they addressed the reported barriers, how practical each option was to implement, and the additional risks of diversion and misuse.

In this report the following conclusions were reached:

- Academic researchers use both SCRA and the compounds without CB₁ activity that are unintentionally caught by the third generation generic definition. The barriers to research in academia mainly stem from limited resources, be it time or money caused by the structure of academic grants. It

takes roughly a year to obtain a domestic licence for a new research project at a substantial cost in comparison to the total grant. These barriers can cause a loss of opportunity as it is harder for the UK to participate in a global research community.

- Pharmaceutical companies reported using non-SCRA compounds that are caught by the third generation SCRA generic definition. The main reported barriers to research stem from the number of controlled compounds, i.e. having to apply for multiple licences, safe storage, record keeping and moving substances across borders. This is causing international pharmaceutical companies to consider moving operations to countries with fewer restrictions.
- CROs commonly investigate compounds controlled in the UK as SCRA. The main barriers to research for Contract Research Organisations (CROs) are moving compounds across borders and international collaboration. This is caused by the regulations requiring safe keeping, record keeping and paperwork for moving compounds. This is causing a loss of opportunity as companies look to countries where it is easier to carry out this research.
- Typically, 100mg of a compound or less is needed for the initial stages of drug research in industry and academia. Within industry it is usually stored in a format where the compound is unrecoverable whereas this is not necessarily the case in academic settings.

The ACMD has made the following recommendations:

Recommendation 1

To ensure that proposed changes only apply to legitimate research, the ACMD recommends that the Home Office defines the term 'research organisation'.

Lead organisations: Home Office.

Measure of impact: This will have been implemented by a change to the Misuse of Drugs Regulations 2001 (MDR).

Recommendation 2

The ACMD recommends that the MDR should be amended to permit such 'research organisations' to produce/possess/supply/offer to supply a 100mg *de minimis* limit for compounds caught under the synthetic cannabinoid generic definition of the Misuse of Drugs Act 1971 (MDA) and the MDR.

Lead organisations: Home Office.

Measure of impact: This will have been implemented by a change to the MDR.

Recommendation 3

The ACMD recommends that the MDR should also be amended to permit 'research organisations' defined in recommendation 1 to import/export up to 100mg of synthetic cannabinoids, except those that come under international control.

Lead organisations: Home Office.

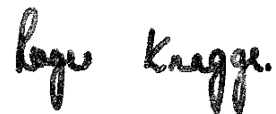
Measure of impact: This will have been implemented by a change to the MDR.

We look forward to discussing the enclosed report with you in due course.

Yours sincerely,



Professor Owen Bowden-Jones
Chair of ACMD



Professor Roger Knaggs
Chair of Barriers to research working group