Home Office

Rt Hon Chris Philp MP
Minister of State for Crime, Policing and Fire
2 Marsham Street
London SW1P 4DF
www.gov.uk/home-office

Prof Owen Bowden-Jones,
Chair, Advisory Council on the Misuse of Drugs (ACMD)
Prof Simon Thomas,
Chair of the NPS Committee, ACMD
C/o 1st Floor,
Peel Building
2 Marsham Street
London
SW1P 4DF

By email: ACMD@homeoffice.gov.uk

12 December 2022

Dear Owen,

BARRIERS TO RESEARCH

Thank you for your report of 30 July 2021 entitled "Considerations of barriers to research Part 1: Synthetic cannabinoid receptor agonists (SCRA)" and I am sorry for the delay in replying to you. I appreciate the care and attention to detail with which the Council has approached this complex issue. This letter responds to the recommendations of the "Part 1" report and formally commissions "Part 2", a wider review of barriers to research affecting Schedule 1 drugs, which I recognise is already underway.

BARRIERS TO RESEARCH – PART 2 COMMISSION

The Government has a clear policy on tackling the harms of illegal drugs, which cause an estimated £20bn social and economic cost to the UK in today's prices in addition to the human cost. Our 10-year drugs strategy seeks to support people through treatment and recovery in addition to providing an even tougher response to criminal supply chains and the demand that fuels these illegal markets. The overall legislative framework on controlled drugs seeks to control harmful substances whilst enabling appropriate access to those drugs for legitimate medicinal, research and industrial purposes.

The Government wants to ensure that research into controlled drugs continues to expand and will provide the necessary support to ensure the UK remains globally competitive environment for innovation and the development

of new medicines. The Home Office and the Department of Health and Social Care (DHSC) have worked together to consider the advice and next steps.

As you are aware, significant progress has been made over recent years in research and medicines development with controlled drugs both in the UK and globally. Research involving controlled drugs, including Schedule 1 drugs, takes place in the UK under the current legislative and regulatory framework, which includes the Home Office licensing regime. There have been recent examples of medicines based on controlled drugs that have received marketing authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) following an assessment of their safety, quality and efficacy. These include Epidyolex and Sativex, which are derived from the cannabis plant and placed in Schedule 5 and Schedule 4 of the Misuse of Drugs Regulations 2001 ("the 2001 Regulations") respectively.

There have been clinical trials into a range of other controlled drugs, such as those exploring the potential benefits of psilocybin for patients with depression and other illnesses as well as MDMA for those suffering from post-traumatic stress disorder, including military veterans. It is right to look for improvements that can be made to the legislation around controlled drugs and work across Government to create the right regulatory environment to further support such research. However, it is also important to ensure that greater access for legitimate purposes does not increase the risks of harm, diversion and misuse.

As such we would like to formally commission the ACMD to look at the wider barriers to research, also known as Part 2, to consider application to all controlled drugs. We would value the advice of the ACMD on how best to reduce regulatory burdens on:

(a) schedule 1 controlled drugs in general, which may also include SCRAs and, in particular, psychedelic drugs including psilocybin; and
(b) all stages of the research process, including clinical trials, building on your 2017 advice.

I recognise that, in its consideration of Part 1, the ACMD sought the views of the research sector including pharmaceutical companies and hope that, in its consideration of Part 2, the ACMD can again seek views from researchers. We would particularly welcome the ACMD's views on the potential options available to extend Schedule 2 status for research purposes to all Schedule 1 drugs. I recognise that this is a complex topic and, should the Council consider it is appropriate, I would welcome any short-term proposals while you consider longer-term possibilities.

BARRIERS TO RESEARCH – PART 1 REPORT

A summary of the ACMD recommendations is set out below:

Recommendation 1

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

Recommendation 2
The ACMD recommends that the 2001 Regulations 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 2001 Regulation.

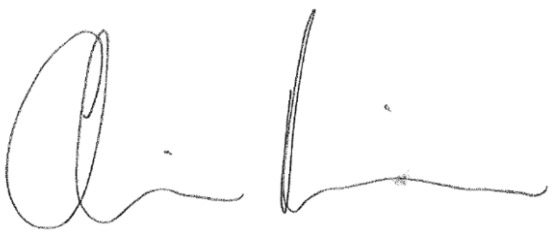
Recommendation 3
The ACMD recommends that the 2001 Regulations should also be amended to permit 'research organisations' defined in recommendation 1 to import/export up to 100mg of synthetic cannabinoids, except those that come under international control.

The Government agrees with the aims identified by the ACMD of enabling greater access with fewer regulatory burdens for legitimate research purposes whilst ensuring that the legislation and licensing system continues to tackle harm, diversion and misuse. We accept in principle the need to amend the legislative framework to achieve these aims. However, we consider that it is not practical to set out a wide-ranging definition of "research organisation" in the manner proposed. We also intend that any reforms should, if possible, encompass Schedule 1 drugs in general, rather than undertaking reform for SCRAs in isolation, subject to an assessment of the risks and any mitigations.

Therefore, in commissioning Part 2, we intend that SCRAs can be considered alongside other Schedule 1 drugs. The Government will then consider and respond to the barriers to research advice in its totality.

I look forward to receiving the recommendations from the ACMD on the Part 2 review and Home Office officials stand ready to assist as necessary.

Yours sincerely,



Rt Hon Chris Philp MP
Minister of State for Crime, Policing and Fire