Briefing: removing barriers to legitimate research

This briefing was prepared by the British Pharmacological Society (BPS) and the Academy of Medical Sciences (AMS) to inform a Main Chamber debate on a motion on access to psilocybin treatments, to be held on 18 May 2023.

Context

Schedule 1 to the Misuse of Drugs Regulations 2001 is a list of controlled substances thought to have no medicinal value and considered to have a high probability for abuse, such as LSD and psilocybin. These substances are tightly regulated, and they may be used for research only under a Home Office licence – but we know from our members and Fellows that this barrier imposes financial and logistic restrictions, thereby dissuading or preventing researchers from studying them.

However, the judgement that these substances have no medicinal value is based on historical knowledge – and once a substance is in Schedule 1 there is no standard process for re-examining current scientific evidence and rescheduling it. Substances with abuse potential that were known to have therapeutic benefit when the scheduling system was implemented (such as heroin) were placed in Schedule 2. The main difference compared to Schedule 1 is the ease of access to researchers: recognised institutions (such as University research departments) are able to carry out research on Schedule 2 compounds without a Home Office licence, but they are still subject to requirements such as safe storage. Drugs that are considered to have high medicinal value and low risk of harms are listed in Schedules 3-5, with little to no impact on research and therapeutics.

There is increasing evidence of potential medicinal value of certain Schedule 1 substances - for example, in the studies that have been possible, psilocybin has shown potential benefits in treating depression and addictions. This emerging potential medicinal value is at odds with the inflexibility of Schedule 1 and the continued barrier it presents to legitimate research.

Where do we stand?

We believe that the UK controlled drugs regulatory system should be updated to enable bona fide research on substances where medicinal value has yet to be identified or is emerging. While reducing harms to vulnerable individuals is clearly a major intention of the current system, which we would support, Schedule 1 can be a barrier to legitimate research – and therefore to identifying potential benefits to patients. From a practical perspective, the UK already operates a research exemption under Schedule 2. Optimising the use of Schedule 2 through regulatory flexibility would be a pragmatic approach to prevent potentially beneficial compounds being locked away in Schedule 1.

Further, if this issue is not properly addressed, we are also concerned that the UK risks offshoring research to jurisdictions with less onerous regulations. This would be damaging to the government's aim of boosting an innovative UK economy through the life sciences.

Our recommendations

1. We would like to see a formal review of the evidence regarding the potential medicinal value of psychedelics as a class of drugs (including but not limited to psilocybin) to enable prompt decisions about rescheduling.

2. To create a modern regulatory system for controlled drugs for the benefit of patients and to support UK ambitions in life sciences research, we are calling for:
    - An evidence-based approach to all drug scheduling as part of a timely, formal process to review current scientific literature to inform decision-making about moving substances out of Schedule 1.

- The extension of the recognition of 'medicinal value' to explicitly include 'research value', noting that it is difficult to establish medicinal value in the absence of fundamental research.

3. Where substances in Schedule 1 are of untested medicinal or research value, we support measures that would make it easier for researchers to establish this value:
    - Together with other partners in the research community, we worked closely with the Advisory Council on the Misuse of Drugs (ACMD) and Home Office regarding the barriers to research posed by the generic definition of third generation synthetic cannabinoids, resulting in a legal change to this definition. The ACMD also recommended a 'de minimis exemption' for synthetic cannabinoids in research programmes, whereby the small amounts (up to 100mg) of compounds typically used in the initial stages of academic and industry research would be exempt from Schedule 1.

Next steps

In its December 2022 response to the ACMD, the government agreed with the aims "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." As part of this, the government commissioned 'barriers to research - part 2' asking for solutions that capture schedule 1 broadly rather than only synthetic cannabinoids. The Society is engaging with ACMD with regard to our recommendations above – including extension of the de minimis limit for all Schedule 1 compounds.

The British Pharmacological Society is the primary UK learned society concerned with research into drugs and the way they work. The Society has over 4,000 members working in academia, industry, regulatory agencies, and the health services, and many are medically qualified. The Society covers the whole spectrum of pharmacology, including laboratory, clinical, and toxicological aspects. Pharmacology is a key knowledge and skills base for developments in the pharmaceutical and biotech industries, and is therefore fundamental to a thriving UK industry and R&D. These skills allow members of the Society to identify therapeutic areas of clinical need, develop novel treatments that target these areas and ensure these new treatments are incorporated into healthcare practice bringing benefit to patients. The Society publishes three scientific journals: the British Journal of Pharmacology, the British Journal of Clinical Pharmacology, and Pharmacology Research and Perspectives.

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